MASON HAYES & CURRAN

Life Sciences Sector Update

In Brief

Summer 2024

Welcome

Welcome to the summer edition of our Life Sciences Sector Update series. In this issue, we examine a selection of topics and trends impacting our clients.

First up, in the above video, Products partner Jamie Gallagher introduces our latest Digital Health Mid-Year Review for 2024 which covers the latest trends, regulatory updates and emerging policies in EU digital health. Download your copy now.

Other popular insights featured in this edition include:

- Regulating Medical Devices in the EU and UK
- Injuncting a UK Approved Body
- AI and Digital Health Products – EU Product Liability Reform
- Court Grants BMS Injunction Pending Appeal Decision

Key Contacts

Michaela Herron
Partner,
Head of Product Regulatory
and Head of Life Sciences
mherron@mhc.ie

Jamie Gallagher
Partner, Product Regulatory
jamesgallagher@mhc.ie

Contact our Life Sciences Sector team

Regulating Medical Devices in the EU and UK

Jamie Gallagher
Partner, Product Regulatory
jamesgallagher@mhc.ie

Michaela Herron
Partner, Head of Life Sciences and Head of Products
mherron@mhc.ie

The regulatory landscapes governing medical devices within the European Union (EU) and the United Kingdom (UK) have seen significant developments in recent years. With the EU's implementation of a Medical Devices Regulation and In-vitro Diagnostic Medical Device Regulation, and the UK's regulatory transition post-Brexit, industry stakeholders must now track separate and diverging requirements in these markets. This article provides an overview of the regulatory frameworks in both jurisdictions, highlighting key amendments, areas of divergence, and their implications for stakeholders.

European Union's regulatory landscape

Within the EU, medical devices are tightly regulated to ensure their safety and performance throughout their lifecycle, from pre-market evaluation to post-market surveillance.

The regulatory framework for medical devices prior to 2021 consisted of three directives:

- Directive 93/42/EEC, (the MDD)
- Directive 90/385/EEC (the AIMDD), and
- Directive 98/79/EC (the IVDD)

These Directives have been replaced by Regulation (EU) 2017/745 (the MDR), which covers both general and active implantable devices, and Regulation (EU) 2017/746 (the IVDR), which covers in vitro diagnostic medical devices, or IVDs.

The reform followed a series of safety issues associated with certain medical devices, such as metal-on-metal hip implants and PIP breast implants.

United Kingdom's regulatory transition

The MDR was originally due to enter into application on 26 May 2020, but its date of application was postponed one year until 26 May 2021 due to the COVID-19 pandemic. The UK was a member of the EU when the MDR was drafted and had actively participated in the shaping of the regulations before Brexit. However, the delayed implementation of the EU MDR meant that it did not form part of the UK's "retained EU law" at the end of the Brexit transition period, which concluded on 31 December 2020. As a result, medical devices continue to be regulated in the UK using the Medical Devices Regulations 2002, SI 2002/618, which effectively implemented the previous EU MD Directives.

The Medicines and Healthcare Products Regulatory Agency (MHRA) launched a Delivery Plan in 2021 to reform the UK regime for medical devices. This plan covered all parts of medical device regulation from pre-market approval, supply of medical devices to the market and post-market monitoring. The UK government envisages that the new regime would run in parallel with current EU rules, which continue to apply in Northern Ireland.

This is required in order to maintain the UK government's approach on the movement of manufactured goods into Northern Ireland.

The MHRA released a roadmap in January 2024 outlining future reform, to provide clarity and outline opportunities for medical device providers and the industry as a whole. Many of the proposed amendments to the current UK regime outlined in the roadmap align with the MDR/IVDR. However, the MHRA aims to learn from the challenges faced during the implementation of the EU MDR regime in the EU, and possible areas of divergence include:

- Adopting the Global Medical Devices Nomenclature (GDMN) as medical device nomenclature for the UK system while the EU has adopted the European Medical Device Nomenclature (EDMN).
- Removing rarely used routes such as batch verification, product quality assurance and type-examination. Options to strengthen and clarify the conformity assessment requirements are also proposed.
- Adding obligation on economic operators to inform the MHRA of any issues affecting the supply of medical devices on the UK market.
- Specific regulation for software as medical device (SaMD) is proposed as a key area of divergence.
- On implantable devices: expanding the scope, introducing more stringent pre-market requirements, more controlled access and reducing the relevance of equivalence criteria. The UK Government has decided to maintain the existing scope.
- Expanded requirements for re-manufacturing of single-use devices.

MHRA Work Programme: Software and AI as a medical device

In conjunction with these reforms, the MHRA launched a consultation on the future regulation of medical devices in the UK. In particular, Chapter 10 of the consultation proposal provides the possible changes that would be specific to, or have implications for, SaMD.

These changes include, for example:

1. Defining software
2. Modifying the definition of 'placing on the market' to clarify when SaMD is deployed on websites, app stores and via other electronic means, and
3. Defining specific requirements for AI as a Medical Device (AIaMD).

The intention of the MHRA's work programme is that it will set a benchmark for the development of regulation for medical device software in the UK. The work packages aim to ensure that:

- The requirements for software and AI as a medical device provide a high degree of assurance that they are acceptably safe and function as intended, thereby protecting patients and the public.
- The requirements are clear, supported by both clarificatory guidance and streamlined processes that work for software, as well as bolstered with the tools to show compliance, for instance, via the designation of standards.
- Friction is taken out of the market by working with key partners like the National Institute for Health and Care Excellence and NHSX to align, de-duplicate, and combine requirements, ultimately providing a joined-up offer for digital health within the UK. The NHSX is a joint unit bringing together the Department of Health and Social Care, NHS England and NHS Improvement to drive digital transformation of care.

The MHRA's work programme includes eleven work packages across two workstreams:

1. Key reforms across the SaMD lifecycle, and
2. Further challenges that AI can pose to medical device regulation.

It is anticipated that much of the reform required to meet the objectives in the work packages will be in the form of clarification-based guidance, standards, or processes rather than secondary legislation.

Some key elements of the eleven work packages are:

- **Qualification** - Ensure that medical device regulations are broad enough to capture relevant software and protect patients and the public.
- **Classification** - Ensure that classification rules can closely track the risk that SaMD poses, but also impose proportionate safety and performance requirements and incorporate enough flexibility to address novel devices.
- **Pre-market** – Ensure that SaMD is safe, effective and of requisite quality before being placed on the market, that any pre-market requirements are sufficiently clear and appropriate for SaMD, and that there are appropriate registration requirements for a robust post-market surveillance system.
- **Post-market** – Ensure a robust post-market surveillance system with a clear safety signal to efficiently deal with, and thoroughly capture, adverse SaMD incidents is in place. Ensure SaMD functions as intended via use of real-world evidence, maintains performance and clearly outlines change management requirements and processes.
- **Cyber Secure Medical Devices** - Articulate how cybersecurity issues can translate to SaMD safety issues and ensure this is adequately reflected in both SaMD pre-and post-market surveillance requirements. Cooperate with other relevant bodies, for example, the Connected Medical Devices Security Steering Group for consistency of approach.
- **Mobile Health, and Apps** - Collaborate across government via other work packages to ensure that the SaMD market provides further safety, effectiveness, and quality assurance.

Further announcements

More recently, the MHRA has also announced a suite of further initiatives designed to set the UK apart from the EU as a home for the development and commercialisation of innovative healthcare technologies. These initiatives include:

- **AI Airlock**: Announced in October, this regulatory sandbox aimed at understanding and mitigating risks associated with AIaMD prior to placing on the market will include four to six projects to test regulatory issues in clinical settings. The objective is to identify challenges and share findings to aid regulatory and funding efforts. MHRA emphasises collaboration and transparency, with no guarantee of regulatory conformity. Applications will open after a webinar in June 2024, with an associated pilot programme involving partners like Team AB and the NHS intended to ensure consistent regulatory interpretation.
- **Impact of AI on regulation**: The MHRA published a policy paper in April 2024 outlining the potential impact of AI on medical products regulation. The paper states that many low-risk AI products will be reclassified for greater scrutiny, enhancing user safety. The paper also outlined MHRA plans to use machine learning to streamline document assessments, allowing human experts to focus on critical evaluations.

- **International recognition**: The MHRA recently announced plans to incorporate approvals from third countries and MDSAP certificates alongside UKCA marking until June 2030. A Comparable Regulator Countries framework would tap into global regulatory expertise, including the FDA, EU member states, Health Canada, and the Australian TGA. Reliance on other regulators' assessments would provide for faster UK approvals, focusing MHRA resources on innovation. Different risk classifications and documentation formats would need to align with UK regulations, and operational details would be developed with industry input. Certain product categories would be excluded from this framework, transitional arrangements for UKCA marked devices would be developed and the regulatory status of products on the market in Northern Ireland would remain unaffected.

Comment

It is clear that the MHRA is seeking to position the UK as a leader in the regulation of high-tech healthcare products by establishing a streamlined yet robust regulatory framework. Once planned changes are eventually enacted, it will be interesting to see how, or if, the future regime on the regulation of this sector in the UK differs to that in the EU. While the EU and UK share common objectives of enhancing medical device safety and fostering innovation, disparities will now exist in their regulatory approaches. Key areas of divergence include naming conventions and standards, conformity assessment procedures, and specific regulations for AI-driven devices. However, both jurisdictions recognise the importance of transparency, patient safety, and regulatory collaboration in shaping the future of medical device regulation.

As the regulatory landscape continues to evolve, stakeholders must navigate the complexities of compliance and stay abreast of regulatory updates. Ultimately, a harmonised approach to medical device regulation, balancing innovation with safety, will benefit patients, healthcare providers, and industry stakeholders alike.

Injuncting a UK Approved Body

Key principles from a recent case

Aisling Morrough
Senior Associate,
Product Regulatory & Liability
amorrough@mhc.ie

Jamie Gallagher
Partner,
Life Sciences and Product Regulatory
jamesgallagher@mhc.ie

In a significant judgment for public authorities and regulatory bodies, the Court of Appeal of England and Wales allowed the appeal in *British Standards Institution v RRR Manufacturing PTY Ltd*. The Court considered the principles applicable to interim relief applications against public authorities. While this is a decision of the English and Welsh courts, it is still important and of potential persuasive authority in Ireland. This is due to the shared common law tradition with England and Wales. The judicial review application was taken by the British Standards Institution (BSI) to challenge interim relief obtained against it by RRR Manufacturing PTY Ltd (RRR). By prohibitory and mandatory orders, BSI was (a) prevented from suspending the UKCA certification for RRR's small portable defibrillator medical device (the device) and (b) required to renew the UKCA certificate at a later date, irrespective of its concerns about the device's safety and performance.

The facts

BSI is an 'approved body' in the UK appointed by the Medicines and Health Regulatory Agency (MHRA). It has the power to award, suspend and revoke UKCA certificates under the UK Medical Devices Regulations 2002[1].

The device had both CE and UKCA certification permitting it to be sold in both the EU and UK markets. However, following concerns raised by the MHRA regarding the device's safety, BSI initiated a technical surveillance review of the device's UKCA certificate. In its subsequent decision, BSI identified a number of major and minor non-conformities with the device to be addressed through corrective action plans (CAPs). RRR exercised a right of internal appeal to BSI. This appeal was dismissed. Subsequently, BSI issued a further decision justifying its conclusion. Based on these two decisions, BSI decided to suspend the device's UKCA certification.

RRR applied for judicial review challenging BSI's decisions. It sought an expedited hearing to prevent BSI from withdrawing its UKCA certificate. The grounds for its application for interim relief were that suspending the device's certificate, on the basis of allegedly unlawful decisions, would cause serious and potentially irreversible harm to RRR, both in the UK and in other jurisdictions.

The judgment

RRR's four grounds of claim were:

- Illegality
- Procedural unfairness
- Irrationality, and
- Fettering of discretion

1. *Whereas the EU Medical Devices Regulation (2017/745) (MDR) is now applicable in EU Member States and Northern Ireland, the UKCA requirements for medical devices regulated under the UK Medical Device Regulations 2002 are based on requirements derived from the MDR's predecessor, Directive 93/42/EEC on medical devices (MDD).*

In considering the balance of convenience, the judge applied the principles governing the grant of interim relief in judicial review proceedings as set out in *American Cyanamid Co v Ethicon Limited*[2] modified as appropriate for public law cases. In doing so, she concluded that the balance of convenience favoured maintaining the status quo. She directed that BSI be restrained from suspending or withdrawing the device's UKCA certificate until after a decision on the substantive claim. She also directed that BSI maintain the device's certification, which was shortly due to expire and for which renewal was not automatic, pending determination of the claim.

In reaching her decision, the judge acknowledged that public health and safety is of paramount concern. However, she found no evidence that the device was a current risk on health and safety grounds. She also noted that the MHRA had the power to investigate the device if it was shown to be a risk to public health and safety. The judge further noted that news of the suspension would spread quickly and that RRR would suffer considerable commercial and reputational harm as a result. The judge refused BSI's permission to appeal.

Grounds of Appeal

BSI appealed the decision on the following three grounds:

- The judge misunderstood both the burden of proof under the relevant regulations, and what it was that had to be proved. BSI argued, amongst other things, that the judge was wrong to decide that there was no evidence that the device was a current risk on health and safety grounds. It further argued that it was not for BSI to satisfy the court that the device was unsafe. Rather, it was for RRR to satisfy BSI that the device was safe and met all the essential requirements
- The judge was wrong to grant a mandatory injunction requiring BSI to renew the device's UKCA certification at a future date. BSI argued, amongst other things, that a public authority should not be restrained from discharging its functions in good faith. This was particularly relevant in the context of a mandatory order. BSI contended that such an order would require it to act in a way it considers unsafe and contrary to the public interest
- The judge should have reserved the costs of the interim application until the outcome of the claim was known

Court of Appeal judgment

The Court of Appeal held that all three grounds of appeal should be allowed. Accordingly, the Court of Appeal set aside the prohibitory order restraining suspension of the UKCA certificate. The Court of Appeal also set aside the mandatory order requiring BSI to renew the UKCA certificate at a later date. Additionally, the costs order was set aside.

In her leading judgment, Lady Justice Laing outlined the underlying principles which should have been applied to the facts of the case as follows:

- First, that great weight must be given to the protection of public health
- Second, in accordance with the medical device regulatory framework, the manufacturer must satisfy the approved body that a device is safe and effective
- Third, the court should also give great weight to the assessment of the relevant material by the expert regulator

1. *[1975] AC 396*

In light of those considerations, the Court of Appeal affirmed that, in determining where the balance of convenience lies in a public law case, two important factors are that:

- The court will not readily restrain a public authority from exercising its powers in good faith. Even if a claim passes the threshold test of raising a serious issue to be tried, if there is not a strong *prima facie* case on the merits, this will be a significant factor in the balance of convenience against the grant of an injunction
- Maintenance of public health is a very important objective and must carry great weight in the balancing exercise

Conclusion

This judgment reaffirms the principles to be applied in interim relief applications against public authorities. It confirms that, in the absence of a strong *prima facie* case, the courts should be slow to grant interim relief against a public authority that is exercising its powers in good faith. It also confirms that the courts should afford significant weight to the protection of public health and safety in determining the balance of convenience. While this is a decision of the Court of Appeal of England and Wales, it is still important and of potential persuasive value in Ireland as a common law EU jurisdiction. This is particularly so given that the underlying principles and legal tests applied in this instance are largely the same as those that would be applied in an Irish law context. The judgment can be found online.

AI and Digital Health Products: EU Product Liability Reform

Michaela Herron
Partner,
Head of Product Regulatory and
Head of Life Sciences
mherron@mhc.ie

Jamie Gallagher
Partner,
Life Sciences and Product Regulatory
jamesgallagher@mhc.ie

As part of its holistic approach to AI policy, the European Commission has proposed a package of reforms to adapt EU product liability rules to the digital age and AI, including through the revision of the Product Liability Directive 85/374/EEC (the PLD). As discussed in our previous article on the PLD, this revised Directive is intended to be complementary in nature to current EU product safety frameworks, such as:

- The EU Medical Devices Regulation (EU) 2017/745 (MDR)
- The In-Vitro Diagnostic Medical Device Regulation (EU) 2017/746 (IVDR), and
- The recently adopted AI Act

These interlinked frameworks give rise to a complex new legislative environment that stakeholders must navigate with care. We highlight some important connections between these frameworks that developers of software medical devices that will be regulated as AI systems should be mindful of.

Broader scope of the PLD

The PLD seeks to update the EU's strict liability regime applicable to products, including software and by extension, AI systems. Accordingly, claims for damage allegedly caused by AI-enabled digital health products and services will fall within the scope of the PLD. This is because the PLD expands the definition of a 'product' to include software:

"'product' means all movables, even if integrated into, or inter-connected with, another movable or an immovable; it includes electricity, digital manufacturing files, raw materials and software".

While the term 'software' is not defined in the PLD, the recitals to the PLD make clear that it applies to software of all kinds, including:

- Operating systems
- Firmware
- Computer programmes
- Applications, and
- AI systems

It also acknowledges that software is capable of being placed on the market as a standalone product and may subsequently be integrated into other products as a component. Accordingly, software will be a product for the purposes of applying no-fault liability under the PLD. This applies irrespective of the mode of its supply or usage and whether it is stored on a device or accessed through a communication network, cloud technologies or supplied through a software-as-a-service model.

Insofar as an AI system qualifies as a 'product' and 'software', it is proposed to fall within the scope of the PLD. At a high-level, this will mean that the PLD will apply to most, if not all, consumer or public-facing systems, or systems that are components of hardware that qualify as a physical 'product'. Accordingly, digital health products and services delivered using AI-enabled technologies such as wearable devices, telemedicine platforms and health apps will be affected.

Two noteworthy exclusions regarding the scope of the PLD are as follows:

- The new product liability rules contained in the PLD will apply to products placed on the market or put into service 24 months after its entry into force. The current Product Liability Directive 85/374/EEC will be repealed with effect from 24 months after the PLD's entry into force. However, it will continue to apply to products placed on the market or put into service before that date.
- The PLD will not apply to pure information, such as the content of digital files or the mere source code of software. It will also not "apply to free and open-source software that is developed or supplied outside the course of a commercial activity" unless it is subsequently integrated by a manufacturer as a component into a product in the course of a commercial activity.

Defectiveness

Under the PLD, the criteria for determining the defectiveness of a product, including an AI system, will be expanded. Some of these additional criteria, which are non-exhaustive in nature, are particularly relevant to AI systems and link back to AI Act requirements:

- In the first instance, the PLD provides that a product will be considered defective "*if it does not provide the safety that a person is entitled to expect or that is required under Union or national law*". Consequently, an AI system may be deemed defective for the purposes of a product liability claim by virtue of being non-compliant with requirements under the AI Act, the MDR and/or the IVDR.
- Additional defectiveness criteria specified under the PLD include a product's interconnectedness, self-learning functionality and safety-relevant cybersecurity requirements.
- In reflecting the relevance of product safety and market surveillance legislation for determining the level of safety that a person is entitled to expect, the PLD also provides that, in assessing defectiveness, interventions by competent authorities should also be taken into account. This includes "*any recall of the product or any other relevant intervention by a competent authority or by an economic operator as referred to in Article 8 relating to product safety*".

Accordingly, an AI-enabled product's compliance with requirements under the AI Act, the MDR and/or the IVDR and interventions by competent authorities in respect of same, will weigh in the balance in terms of assessing the 'defectiveness' or otherwise of an AI system.

Rebuttable presumption - defectiveness

Under the PLD, the burden remains on a claimant to prove:

- The defectiveness of the product
- The damage suffered
- The causal link between the injury or damage sustained, and the allegedly defective product

These elements must be proven in accordance with the standard of proof applicable under national law in the relevant Member State(s). The PLD acknowledges, however, that injured parties are often at a disadvantage compared to manufacturers in terms of accessing and understanding information about how a product was produced and how it operates, particularly in cases involving technical or scientific complexity. Accordingly, the PLD introduces a rebuttable presumption of defectiveness where:

1. The claimant demonstrates that the product does not comply with mandatory product safety requirements laid down in Union law or national law.
2. The claimant demonstrates that the damage was caused by an "*obvious malfunction*" of the product during "***reasonably foreseeable***" use or under ordinary circumstances.
3. A defendant fails to comply with a court order to disclose relevant evidence at its disposal.

In the context of AI systems, the rebuttable presumption of defectiveness triggered under the PLD by a product's non-compliance with mandatory product safety requirements laid down in Union law or national law could therefore be triggered by an act of non-compliance with requirements under the AI Act, the MDR and/or the IVDR.

Rebuttable presumption - causation

The PLD also provides for the presumption of a causal link between a product's alleged defectiveness and the damage suffered, where it has been established that the product is defective, and the damage caused is of a kind typically consistent with the defect in question.

A rebuttable presumption will arise where a national court must presume a product's defectiveness or the causal link between its defectiveness and the damage suffered, or both, where, despite the disclosure of evidence by a manufacturer, and taking all relevant circumstances into account:

- The claimant faces excessive difficulties, in particular due to technical or scientific complexity, in proving the product's defectiveness or the causal link between its defectiveness and the damage, or both, and
- The claimant demonstrates that it is likely that the product is defective or that there is a causal link between the defectiveness, the damage, or both.

On the interpretation of 'excessive difficulties', Recital 48 of the PLD refers to AI systems specifically. It provides that in determining technical or scientific complexity, national courts must do this on a case-by-case basis, taking into account various factors, including:

- The complex nature of the technology used, such as machine learning.
- The complex nature of the causal link such as a link that, in order to be proven, would require the claimant to explain the inner workings of an AI system.

It further provides that, in the assessment of excessive difficulties, while a claimant should provide arguments to demonstrate excessive difficulties, proof of these difficulties should not be required. For example, in a claim concerning an AI system, the claimant should neither be required to explain the AI system's specific characteristics nor how those characteristics make it harder to establish the causal link.

Manufacturer's control

The PLD introduces various new provisions that recognise that, in the case of technologically sophisticated products, a manufacturer's responsibilities do not necessarily crystallise at the factory gates. This is particularly significant for connected products, where the hardware manufacturer retains the ability to supply software updates or upgrades to the hardware by itself or via a third party.

The PLD provides that the developer or producer of software, including an AI system provider, should be treated as a manufacturer. While the 'provider of a related service' is recognised as an economic operator under the PLD, related services and other components, including software updates and upgrades, are considered within the manufacturer's control where they are integrated, inter-connected or supplied by the manufacturer or where the manufacturer authorises or consents to their supply by a third party.

A 'related service' is defined in the PLD as "a digital service that is integrated into, or inter-connected with, a product in such a way that its absence would prevent the product from performing one or more of its functions". For example, where a manufacturer consents to the provision by a third party of software updates for its product or where it presents a related service or component as part of its product even though it is supplied by a third party. However, a manufacturer isn't considered to have consented to the integration or interconnection of software with its product merely by providing for the technical possibility to do so, or by recommending a certain brand or by not prohibiting potential related services or components.

Additionally, once a product has been placed on the market, it is considered within the manufacturer's control insofar as it retains the technical ability to supply software updates or upgrades itself or via a third party.

This means that manufacturers of products with digital elements may be liable for damage arising from changes to those digital elements that occur after the physical product is placed on the market. This is a significant shift to more of a 'lifecycle' approach. This aligns with the approach adopted under various pieces of EU product safety legislation, including the MDR, where manufacturers must continuously evaluate the impact of software updates and upgrades in products on the market. The consequence for manufacturers of AI-enabled products is that greater attention will need to be paid to:

- The degree of control it exercises over its products once placed on the market.
- Where its products remain within its control, the extent to which changes like software updates and upgrades impact on not just safety but also product liability exposure.
- What 'related services' form part of its products and the level of control exerted over these 'related services', including the nature of the relationship with any third-party providers of related services and the potential consequences of same from a product liability perspective.

Substantial modification

The PLD maintains the general limitation period of 3 years for the initiation of proceedings for the recovery of damages. This limitation period runs from the day on which the injured person became aware, or should reasonably have become aware, of all of the following:

1. The damage
2. The defectiveness, and
3. The identity of the relevant economic operator that can be held liable for the damage.

The PLD contains two modifications to the current 10-year longstop provision in the existing Product Liability Directive. First, an extension to 25 years in certain cases involving latent personal injuries unless the injured person has, in the meantime, initiated proceedings against a potentially liable economic operator. Second, where a product has been 'substantially modified', the calculation of time runs from the date that the substantially modified product has been placed on the market or put into service.

In that regard, the PLD defines 'substantial modification' as the modification of a product after it has been placed on the market or put into service:

1. That is considered substantial under relevant Union or national rules on product safety, or
2. Where relevant Union or national rules do not provide such a threshold, that:
    - Changes the product's original performance, purpose or type without being foreseen in the manufacturer's initial risk assessment, and
    - Changes the nature of the hazard, creates a new hazard, or increases the level of risk.

What amounts to a 'substantial modification' can be quite case specific. However, the reference in the definition to modifications that are "considered substantial under relevant Union or national rules on product safety" engages the AI Act. This is because it contains references to substantial modification in the context of 'high-risk AI systems', i.e. most software medical devices regulated as AI systems owing to the application of MDR, Annex VIII, Rule 11 and Article 6 of the AI Act. One such example is high-risk AI systems that continue to learn after being placed on the market or put into service.

Where no thresholds are provided under the relevant Union or national rules on product safety, for example in cases involving regulated AI systems that are not high-risk under the AI Act, the threshold is assessed by the extent to which the modification changes the product's original intended functions or affects its compliance with applicable safety requirements or changes its risk profile.

We expect that the practical application of these concepts in the context of AI systems will require complex and case-specific analyses on liability exposure and mitigation.

Irrespective of which threshold criteria is applicable to a specific AI-enabled product, AI system providers and providers of products with AI components, will need to carefully track how relevant AI systems are changing and the legal consequences of those changes.

Conclusion

On one hand, digital health stakeholders of products regulated under the MDR and/or the IVDR may be uniquely well-placed to adapt to these changes given their experience of complying with the sophisticated EU medical device regulatory framework. On the other hand, however, the move to bring the EU product liability regime up to speed with updated product safety legislation is likely to give rise to increased litigation risks that will require careful management, particularly for liability exposure in respect of software as a 'product' for the purposes of product liability claims. To prepare for these incoming changes, digital health stakeholders with products on the EU market should carefully consider their potential liability exposure under the PLD.

We would recommend that they carefully analyse their existing product portfolio to:

- Identify what products would fall within the scope of the PLD, including a review of third-party software and 'related services', i.e. digital services embedded in their hardware products.
- Review the warnings and disclaimers provided to users relating to risks or potential harm associated with using their products and related services, particularly having regard to the extended definition of damage.
- Incorporate the necessary screens and protocols into their product roadmaps in order to identify and mitigate EU product liability exposure.

Digital health stakeholders should also review their:

- Product liability insurance to ensure, amongst other things, that their coverage includes all damage envisaged under the PLD. Specifically, they should ensure that coverage extends to destruction or corruption of data and medically recognised damage to psychological health and to ensure that related services are also covered.
- Contractual arrangements with other economic operators to ensure there are adequate liability and indemnity provisions in place. This is particularly important given the new provisions in the PLD around service providers and what is considered to be within the manufacturer's control – even if a third party is carrying out certain tasks or services on their behalf.

Court Grants BMS Injunction Pending Appeal Decision

Gerard Kelly
Partner,
Head of Intellectual Property
gkelly@mhc.ie

The Irish Court of Appeal ruled in favour of Bristol-Myers Squibb (BMS). It granted an injunction restraining Teva from infringing its Supplementary Protection Certificate (SPC) by launching a generic Apixaban product called 'Eliquis'. This injunction will remain in place pending the outcome of its substantive invalidity appeal. The decision means that Teva are prevented from launching its version of BMS' medicinal product, Eliquis. The case is interesting as it is the first to determine granting an injunction pending an appeal where a patent has been held invalid at first instance. We review the court's findings.

The SPC in question extends the exclusive rights BMS enjoys under European Patent (IE) 1 427 415 (the Patent). The Patent expired on 17 September 2022. The SPC is due to expire on 19 May 2026. Apixaban is a DOAC produced by BMS under the brand name Eliquis.

High Court decision

The High Court found the SPC to be invalid at first instance in December 2023. This decision was appealed to the Court of Appeal and a hearing took place in May 2024. A decision is awaited.

In an effort to prevent Teva from launching its competing product while the appeal decision was outstanding, BMS applied to the High Court [1] for an injunction restraining Teva from launching during this time. Mr Justice Barrett refused to renew the pre-trial injunction. This decision was made as he held the patent to invalid.

The initial injunction, granted in February 2023, had restrained Teva from launching, pending the determination of the appeal.

BMS appealed this decision. The parties then agreed to continue the stay on the revocation of the patent until the determination of the appeal. They also agreed to continue the injunction pending the appeal by BMS against the refusal of the injunction. This arrangement was to remain in place until the appeal could be heard and determined by the Court of Appeal. This was based on BMS's commitment to continue to take steps to seek to ensure no other generic is permitted to launch. BMS also agreed not to allow any preparatory steps for launching a generic version of apixaban until the determination of the injunction appeal.

Court of Appeal decision

The appeal of the refusal of the injunction was heard in March 2024. It is that appeal to which this decision relates. The substantive appeal on the merits has also been heard but not yet determined.

This was the first example of an application for an injunction restraining infringement of a patent pending appeal where the patent has been found to be invalid in this jurisdiction. Instead, BMS relied on the English decision of Novartis AG v. Hospira UK Limited[2] which is of persuasive authority in this jurisdiction. In Novartis, an injunction was granted on the basis that the damage to the patent holder was "both more certain to occur and greater in magnitude than the damage to the defendant".

Further, due to the probable entry of two other generic companies to the market, the possibility of the defendant enjoying the benefits of first mover advantage were considered remote. The fact that the market will have become accustomed to lower prices was a significant factor in the court findings that restoring any monopoly would be, if possible at all, accompanied by harm of other kinds.

The Court of Appeal noted that in England the threshold question is whether the appeal has a real prospect of success. Whereas in Ireland, the question is whether the appellant has an arguable or stateable appeal. However, the Court was satisfied that the fact that the thresholds are different does not alter the principles to be applied to an application of this nature once the relevant threshold is met.

The Court of Appeal ultimate found that it was not possible to protect both BMS and Teva from the risk of injustice but that the balance clearly favoured BMS. It considered the damage to BMS to be more certain to occur and greater in magnitude than the damage to Teva. This was particularly due to the readiness of other generics to launch and the resulting immediate and sharp downward price spiral.

The following points are of particular note for patent owners:

- The Court of Appeal found that the High Court placed "undue weight" on the outcome of the first instance invalidity decision in refusing the injunction.
- The Court of Appeal considered it incorrect to find that the presumption of validity was gone following the first instance decision.
- The Court of Appeal found that the High Court did not have proper regard to BMS's right to exclusivity. It also noted that this right may not be capable of being sufficiently restored should the invalidity appeal succeed.
- The Court of Appeal found that the High Court had failed to recognise the risk of uncompensable damage to BMS in the event of further generic entry and a resulting price spiral.

The Court of Appeal emphasised that the test for adequacy of damages is not simply whether there exists a method to calculate damages. It confirmed that the test is whether the remedy in damages can be said to be *"necessarily commensurate with any possible injury"*. Further, where a court concludes that damages would not be or would be an adequate remedy for a party, this is not decisive. Instead, it is only a factor to be considered in determining where the balance of justice lies.

Conclusion

This decision will come as a disappointment to generics. It could be read as suggesting that no generic can ever launch onto the market until it successfully exhausts the appeal process. This is both an expensive and time-consuming process. The Court of Appeal acknowledges this and says that different facts may alter the equation. It suggests that the best way for the court to minimise the risk of injustice to generics is to seek to expedite the procedures. The court should aim to list the trials and appeals for as early as possible and to deliver judgments shortly thereafter. However, this is possibly little comfort to generics given that the courts are restricted by their workload.

Life Sciences Sector

Ireland is a globally recognised centre of excellence for life sciences, pharma and medtech companies, ranging from global multinationals to an increasing number of vibrant indigenous companies.

Our Life Sciences team, drawn from specialist practice areas across the firm, offers commercial and practical advice to global players and emerging companies alike. Our key strength is our industry knowledge and expertise. Many of our lawyers have backgrounds in industry, science and medicine.

Life sciences companies require a special blend of legal advice and industry knowledge. We advise on a variety of issues from the development, protection and licensing of intellectual property to clinical and regulatory matters.

We also advise on a number of other areas affecting the life sciences sector. In particular, we have deep expertise on the intersection of technology and healthcare law and are one of the few advisors in Ireland with this expertise.

Contact our Life Science Sector team

About Us

We are a business law firm with 120 partners and offices in Dublin, London, New York and San Francisco.

Our legal services are grounded in deep expertise and informed by practical experience. We tailor our advice to our clients' business and strategic objectives, giving them clear recommendations. This allows clients to make good, informed decisions and to anticipate and successfully navigate even the most complex matters.

Our working style is versatile and collaborative, creating a shared perspective with clients so that legal solutions are developed together. Our service is award-winning and innovative. This approach is how we make a valuable and practical contribution to each client's objectives.

What Others Say

Our Life Sciences Team

"Energetic, passionate and on top of their sector".

Legal 500, 2023

Our Life Sciences Team

"They assess complex situations in a balanced manner with an intuitive ability to recognise and understand the cases. They get the job done efficiently but always in a warm and friendly way."

Chambers & Partners, 2023