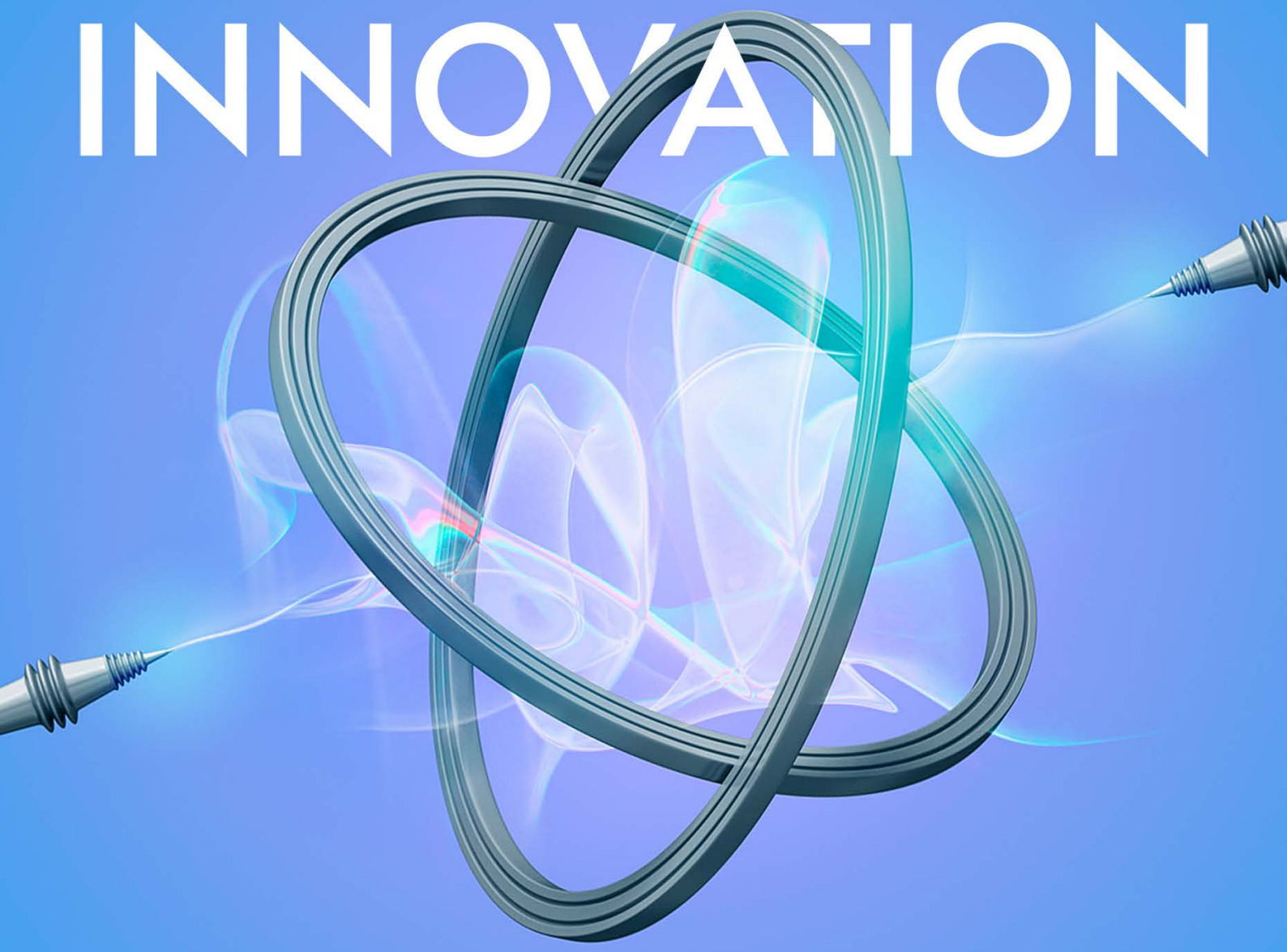
IN
INTERNATIONAL NEWS
ISSUE 60

SPOTLIGHT ON INNOVATION



A Look Inside...

UNLOCKING POTENTIAL: ALTERNATIVE FUNDING SOURCES FOR GROWING COMPANIES

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McDermott Will & Emery

INTERNATIONAL NEWS

IN THIS ISSUE

A number of major developments have emerged in response to the challenges faced by, and created by, innovative companies.

The new EU Unified Patent Court (UPC) has revolutionised patent protection. It enables innovators to obtain patent protection in the majority of EU Member States with just one application to the European Patent Office. This is a significant improvement on the old system, under which companies had to register national patents in each Member State individually.

Several new financial instruments have been created to service the particular needs of start-ups and growing companies. Junior capital and subordinated financings, and financing based on annual recurring revenue rather than earnings before interest, taxes, depreciation, and amortization (EBITDA) are just a sample of the options available that may suit a young company better than a simple injection of cash from a bank.

The EU Artificial Intelligence Act came into force in March this year, introducing a new regulatory framework for AI systems and models. The Act has broad geographic and sectoral reach but has a significant impact on the health and life sciences industries. Its implementation is a timely reminder that innovative companies with an international outlook need to be aware of the multiple, overlapping regulatory systems that impact their business. The conduct of global clinical trials, for example, requires multiple regulatory approvals in a process that can quickly become complex and expensive.

Businesses facing challenges like these need to work with advisors who embrace all the innovative tools available to them to support their clients efficiently and cost-effectively. The legal sector has embraced the opportunities afforded by technology and, although many tools still require considerable regulatory scrutiny, the most client-focused firms have already created bespoke solutions that deliver significant savings in both time and money.

Please contact the authors directly if you have any comments on our articles, or would like to discuss any of the issues raised.

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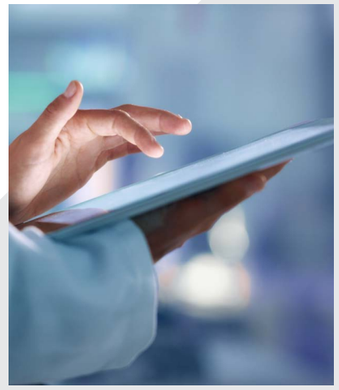

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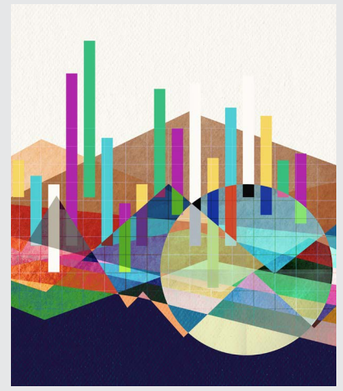

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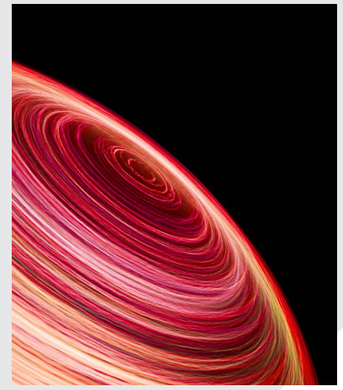

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UNLOCKING POTENTIAL: Alternative Funding Sources for Growing Companies

Aymen Mahmoud and Sophie Rezki

A major challenge for growing companies and start-ups is the constant need for financing that will unlock their potential and maximise value for stakeholders.

The now-standard model of cashflow lending is often inadequate for business bringing innovative products and services to market. It relies on historical earnings, and multiples driven by those earnings, limiting fast-growing early-stage businesses. Alternative sources have evolved to provide key support for game-changing businesses on their path to profitability.

ANNUAL RECURRING REVENUE (AAR) BASED FINANCING

Whilst not new, there has been an increasing number of ARR financings recently. They rely on the recurring revenues of companies that are not yet earnings before interest, taxes, depreciation, and amortisation (EBITDA)-positive but have major growth potential.

Unlike EBITDA financings, ARR financings are based on a forward-looking model and rely on expected increased income and decreased cost or churn. As a result, software as a service (SaaS) and subscription-based model businesses have embraced ARR financings enthusiastically.

The forward-looking approach also allows financiers to closely track the financial growth of the business and variations in its customer base, increasing their inclination to provide support that will reduce perceived risk.

ARR financings provide a great opportunity for revenue-based financiers that are patient in waiting for financial maturity and even willing to help drive that growth.

JUNIOR CAPITAL AND SUBORDINATED FINANCINGS

Junior capital uses the significant resources available through new subordinated debt or mezzanine financings.

Junior capital often bears a higher risk than other sources of financing, given its subordinated features, meaning higher interest rates and/or equity conversion features. Businesses should therefore carefully evaluate the need for additional funding in the future, taking into consideration debt servicing and equity dilution risks.

> “ ARR financings provide a great opportunity for revenue-based financiers.

Nevertheless, junior financings can align the parties' interests as repayment and returns are dependent on the businesses' future cashflow and success. This often leads to increased partnership, value creation, innovation, and sustainable growth.

> “ Junior financings can align the parties' interests.

HYBRID PRODUCTS

Hybrid financing can provide much needed flexibility. A traditional public markets high-yield issuance combined with the ever-popular private credit product has been put to good use by borrowers wanting to blend execution certainty with optimised economics.

While the high yield markets are comparatively generously endowed with available capital during limited periods, recent history has taught borrowers that these markets cannot offer unlimited certainty.

What is clear from these examples is that financing models have evolved. A simple, hands-off injection of funds from a bank is no longer the norm; the most popular financing models are those that provide incentives for all parties to work together to promote growth. There are likely to be even more novel financing structures in the near future as stakeholders refamiliarise themselves with the more expensive debt landscape pre the most recent global financial crisis.

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LEVERAGING GLOBAL CLINICAL TRIAL DATA:
Navigating Domestic Regulations

James R. Ravitz, Paul S. Gadiock, Sharon Lamb, Marissa Hill Daley and Bella North

Conducting global clinical trials offers several advantages, including diverse patient populations, accelerated application timelines, and cost-effectiveness. But securing domestic regulatory approvals for the use of the resulting data can be complex.

> **Collaboration between legal experts and pharmaceutical stakeholders is essential.**

The US Food and Drug Administration (FDA), the European Medicines Agency, and the UK Medicines and Healthcare Products Regulatory Agency all have similar data standards and expect foreign data to meet similar standards of quality, reliability, and integrity as data generated domestically. But variations in trial design, patient demographics, and regulatory requirements across countries can complicate approval processes.

In most jurisdictions, sponsors must demonstrate that the trial data is applicable to the relevant population and complies with the International Council for Harmonisation (ICH) Guidelines for Good Clinical Practice standards. In the United States, pre-submission meetings with the FDA can help clarify expectations and address any concerns regarding the foreign data. Sponsors, CROs, and other clinical trial service providers (collectively "conducting parties") should meticulously document the conduct of global trials, including protocols, informed consent forms, and adverse event reports. (View our latest webinar here)

The FDA may require bridging studies to establish the relevance of foreign data to the US population, and validation of data through on-site inspection or other appropriate means. Where an application is based solely on foreign clinical data, the sponsor must also prove that the studies have been performed by clinical investigators "of recognised competence."

Although the FDA has said that if an application fails to meet any of these criteria it will result in the application not being approvable based on the foreign data alone, the Agency has also said that it will be flexible on this policy, depending on the nature of the drug, device, or biologic, and the data being considered.

> **Conducting parties should document and acknowledge the use of AI at each stage.**

While the FDA has begun to issue guidance on the use of artificial intelligence (AI) in the approval process, its tolerance for AI in the validity of trial data is not yet known. Conducting parties should document and acknowledge the use of AI at each stage of the trial, including if it was used to design the trial. All this information should be included in the description of the data in the application to the FDA. Conducting parties should also track the international regulation of AI, particularly in the jurisdiction where a foreign trial took place.

In Europe, clinical trials must also take into account changing legislation on testing, and in vitro diagnostic tests and devices used in trials. Where these tests and devices are not yet certified, the data generated may also be required for the performance evaluation and investigation of these devices so that additional evidence is required on efficacy.

Conducting parties should monitor the regulation of data from certain regions. For example, in March 2024, a US Senate committee voted to approve a bill that would prohibit federal agencies from contracting with Chinese biotech companies, including Wuxi AppTec, on national security grounds.

The global clinical trials market is projected to reach US$73.2 billion by 2028. Collaboration between legal experts and pharmaceutical stakeholders is essential to streamline the process, secure regulatory approval, and ensure a return on what is always a substantial investment.

MORE FROM McDERMOTT ON FDA AND CLINICAL TRIALS

FDA Proposes Rule to Update Clinical Trial Data Monitoring

FDA Establishes CDER Center for Clinical Trial Innovation (C3TI)

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PROTECTING EMPLOYEES' TAX POSITION AFTER A SPIN-OFF

Rob Marshall

Spin-offs have become increasingly popular with innovative companies as a method of unlocking shareholder value, but the transaction is not always tax-free, particularly for international employees holding equity awards or shares.

The ability to obtain tax-free treatment in the United States for both the company and shareholders in a spin-off is often attractive. However, the transaction is not always tax-free for shareholders located outside the US. When local country criteria are not met, the distribution of spin-co shares is taxable for shareholders.

> "Employees holding equity awards and company shares can be negatively affected.

Significantly, employees holding equity awards and company shares can be negatively affected by a spin-off, which can have a significant impact on morale at a very sensitive time in a spin-co's evolution.

Companies generally take one of two approaches when adjusting equity awards in a spin-off: either a basket approach, where employees hold equity awards from both companies; or a concentration approach, where employees only retain equity awards from their post-spin employer. The basket approach raises more local tax and securities compliance issues than the concentration approach as the employee is holding awards from a company that is not their employer.

"Long" shares held by employees in an employer's plan raise additional issues. The applicable tax analysis mirrors the analysis applicable to shareholders generally, which may or may not be taxable upon distribution, depending on the country. However, the tax result may differ when the shares are held in a trust or where the employee does not yet have full ownership of the shares. In certain cases, a local tax ruling should be submitted, potentially providing the employees with more favourable tax treatment than regular shareholders.

Tax-qualified equity awards also require consideration as the tax-advantaged treatment may be lost for the employees in many countries. For example, in the United Kingdom, Share Incentive Plans (SIPs) and Company Share Option Plans (CSOPs) are common equity awards and a spin-off impacts them differently.

When an employee holds shares in a SIP for five years, the employee may sell the shares without paying income tax or national insurance contributions. However, when a spin-off transaction does not meet the UK "demerger"' rules for a tax-free spin-off, the SIP participants will be subject to taxation on the value of the distributed spin-co shares when they are distributed.

If an employee exercises CSOP options three or more years after grant, that employee doesn't pay income tax at exercise for the difference between the exercise price and the current fair market value of the shares. Any adjustment of the CSOP awards results in the loss of tax-qualified treatment, subjecting the employee to income taxation when the options are exercised. Employees who have already met the three year requirement may therefore prefer to exercise the awards prior to the spin-off.

In most cases, particularly if the communication occurs shortly before the spin-off, employees do not fully understand the ramifications until it is too late to mitigate the tax impact. To avoid this, companies should communicate the tax implications to employees well before the spin-off, taking into account that preparing the analysis, and the requirements for restructuring the employee workforce prior to spin, often take significantly longer than expected.

> "Companies should communicate the tax implications to employees well before the spin-off.

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> High-risk AI systems will need to comply with a raft of additional requirements.

THE IMPACT OF THE NEW EU AI ACT ON THE MEDTECH AND LIFE SCIENCES SECTOR

Sharon Lamb, Dr. Deniz Tschammler and Lorraine Maisnier-Boche

The EU Artificial Intelligence (AI) Act was passed by the European parliament on 13 March 2024 and introduces a new regulatory framework for AI systems and models.

As technology continues to advance almost every aspect of healthcare, so the use of AI has become an increasing focus for developers and the regulators who are racing to keep pace with rapid advancements in technology.

Software (including AI) with a medical purpose is already regulated in Europe and the United Kingdom as a medical device and requires comprehensive assessment before it can be placed on the market under EU Medical Device Regulations 2017 (MDR) and the EU In Vitro Diagnostic Medical Devices Regulation (IVDR).

Despite the existing comprehensive regulatory requirements, there has been concern that the current framework does not fully address the ethical and transparency risks associated with AI. The European parliament is leading the way with the Act, which applies to all sectors but will have significant implications in the life sciences sector, particularly for AI medical device manufacturers. Click here for our general overview of the Act.

Like the General Data Protection Regulation, the Act has global reach; it will apply to providers wherever they are in the world if they place, or put into service, an AI system in the European Union. The Act is also only one piece in the puzzle of new AI-related legislation and will need to be read in the context of changes proposed on product liability and AI liability.

DEFINING AN AI SYSTEM

Over the last few years, it has become popular to describe technologies as artificial intelligence, even where the software may be a fixed or locked algorithm with no adaptiveness.

It will now be important for manufacturers to determine whether their software are truly AI systems with the scope of the Act, which defines an AI system as

"A machine-based system designed to operate with varying levels of autonomy, that may exhibit adaptiveness after deployment and that, for explicit or implicit objectives, infers, from the input it receives, how to generate outputs such as predictions, content, recommendations, or decisions that can influence physical or virtual environments."

The key term here, "infer" is not precise, but the recitals to the Act give helpful context about how it should be interpreted, stating that AI does not include systems based on rules defined solely by natural persons to automatically execute operations. In other words, the Act does not appear to apply to software comprised of rules-based fixed algorithms. Systems that go beyond basic data processing and enable learning, reasoning, or modelling are, however, likely to be caught.

The line here may not always be clear cut, and it appears that the Act will not apply to many current "AI" solutions, which operate using fixed diagnostic algorithms rather than independent or self-learning capabilities, although stabilised systems with incremental learning may be caught.

HIGH RISK AI SYSTEMS

Under the Act, any AI system that is a Class IIa (or higher) medical device, or uses an AI system as a safety component, is designated as "high risk".

The Act also specifies certain types of healthcare AI systems as high risk, whether or not they are medical devices, such as AI systems used by public authorities to evaluate the eligibility of people for essential public services, and AI systems that are emergency healthcare patient triage systems.

WHAT AI MEDICAL DEVICE PROVIDERS NEED TO KNOW

Under the AI Act, high-risk AI systems will need to comply with a raft of additional requirements, many of which overlap with the current rigorous requirements of conformity assessment under the MDR and IVDR

These entirely new requirements include a conformity assessment by a notified body that the AI system meets the requirements under the AI Act, including with respect to the technical documentation and risk management system. During the development of the legislation, there was concern that this "double certification" would lead to significant delay of market entry and double running cost for device manufacturers. The legislators have accommodated these concerns, in part. For medical devices, the Act states that the conformity assessment procedure in the MDR and IVDR must be followed, and that the requirements of the Act will be part of that assessment.

The Act also allows medical device notified bodies to carry out AI conformity assessments, provided that their AI competence has been assessed under the MDR and IVDR. In other words, a single declaration of conformity is proposed, although the precise mechanics for this remain unclear.

Given the well-publicised lack of notified body capacity in the run-up to the implementation of the MDR and IVDR, medical device manufacturers will naturally be concerned to ensure that their existing notified body has been assessed as competent to conformity assess AI systems. If two notified bodies are required, that may risk divergent views on how the same or similar requirements are to be met.

Many of the requirements in the Act also replicate existing requirements in the EU MDR and EU IVDR. For example, the requirements to have a quality management system, technical documentation, and instructions for use.

The AI Act contemplates a single set of technical documentation to include all the requirements, both under the EU MDR and the EU AI Act. However, medical device manufacturers that have already certified their devices under the EU MDR, may need to amend their technical documentation to reflect the additional requirements of the EU AI Act.

Additional requirements for AI systems that are not already in the EU MDR and the EU IVDR include

- Governance and data management requirements for training and testing data sets
- New record-keeping requirements, including the automatic recording of events (logs) over the system's lifetime
- Transparent design requirements so deployers can interpret the output and use it appropriately
- Human oversight design requirements
- Accuracy and cybersecurity requirements.

Where medical device manufacturers are providers or deployers of general-purpose AI models or systems, they will also need to comply with these requirements.

Although legislators have made efforts to attempt to streamline overlap between regulatory frameworks, many questions remain. For example, it is not clear how the substantial modification framework under the AI Act will interact with the MDR and IVDR modification rules.

CONTINUED

Likewise, it is not clear whether devices undergoing a trial (performance evaluation or clinical investigation) will need to be AI Act certified prior to use in the trial.

The Act proposes harmonised standards, but it is not currently clear whether these will overlap or differ from current harmonised standards, such as ISO 13485.

The industry will be keen to see the guidance on these points, and to understand whether the costs and time of a second certification present a barrier to market entry of the most innovative products.

THE IMPACT ON DEPLOYERS OF HIGH RISK AI SYSTEMS

Unlike the MDR and IVDR, which place responsibilities on economic operators in the supply chain, the AI Act also puts responsibilities onto the deployers of AI systems, being any person using an AI system in the course of a business or professional activity, such as hospitals or clinicians. These deployers will have new obligations, including

- Taking appropriate technical and organisational measures to ensure that AI systems are used in accordance with their instructions for use
- Assigning human oversight to competent, trained people
- Monitoring and surveillance
- Maintaining system logs when these are under their control
- Undertaking, where applicable, data protection impact assessments.

IMPACT ON THE USE OF AI SYSTEMS IN THE WIDER LIFE SCIENCES SECTOR

There is increasing use of AI systems across the medicine product lifecycle, from drug discovery through to post market vigilance activities. You can read more about the impact on the wider life sciences sector in our longer *On The Subject*.

IMPLEMENTATION TIMETABLE

The AI Act is likely to enter into force later this year, with a phased implementation period, followed by a phased transition period, before becoming enforceable. Obligations for high-risk AI systems already covered by other EU regulation, such as medical devices, will only come into force 36 months after the Act enters into force.

Whilst this is a relatively generous period, it is worth bearing in mind that the MDR and IVDR had longer implementation periods, and in both cases, these have now been extended.

> **“ The AI Act is likely to enter into force later this year.**

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THE UNIFIED PATENT COURT: A Revolution In Patent Protection

Dr. Henrik Holzapfel, Charles (Chuck) Larsen, Dr. Laura Katharina Woll and Charles de Raignac

Innovative businesses, which generate valuable patents, are benefitting from the speed, geographical reach, and simplicity of the new Unified Patent Court.

The Unified Patent Court (UPC) became operational on 1 June 2023; it has jurisdiction over patent infringement and validity matters in the 17 Member States of the European Union where the Agreement on a Unified Patent Court (UPCA) is in force. Its launch marked a pivotal moment for the protection of intellectual property in Europe and globally.

Companies with business activities in Europe were previously forced to register a “bundle” of national patents across the 27 EU Member States plus countries such as the United Kingdom, Switzerland, or Turkey, which needed enforcement or invalidation campaigns on a country-by-country basis. Now, by submitting a single request to the European Patent Office, the Unitary Patent enables innovators to obtain patent protection in (currently) 17 EU Member States at once, with Ireland, Poland, and other countries possibly joining the UPC system soon. The UPC deals with the infringement and validity of Unitary Patents in addition to conventional European “bundle” patents, thereby creating a fast and cost-effective single enforcement and invalidation mechanism for patents in the Member States that have ratified the UPCA.

> **“ The Unitary Patent enables innovators to obtain patent protection in 17 EU Member States.**

CONTINUED

Infringement proceedings start in the UPC Local Divisions: Düsseldorf, Munich, Hamburg, Mannheim, Paris, Vienna, Brussels, Copenhagen, Helsinki, Milan, The Hague, Lisbon, Ljubljana; and the Nordic-Baltic Local Division, with several seats in Stockholm, Riga, Tallinn, and Vilnius. Revocation proceedings are initiated at the Central Divisions in Paris, Munich, or (as of summer 2024) Milan, depending on the field of technology of the relevant patent. The Court of Appeal has its seat in Luxembourg. The Court panels are multinational, always comprising judges from a number of participating Member States.

A NEW GLOBAL GOLD STANDARD?

Before the UPC, patents in Europe were enforced and challenged on a country-by-country basis, with the possibility of inconsistent national judgements, different evidentiary standards and timelines, or even bifurcation between infringement and invalidity proceedings, as well as limited potential for large damages awards. With the UPC, however, decisions will have effect in all participating Member States, making it possible to challenge or enforce patents in a geographically and economically large market in a single court case. Furthermore, the Court has jurisdiction to decide on validity and infringement in a single action; bifurcation, although possible is, in principle, not envisaged.

A particularly attractive feature for patent holders is the speed of the UPC. In infringement proceedings, the defendant has only three months to file a complete defense; in revocation procedures the defendant has just two months; and cases should go to trial within a year. This puts the UPC ahead of even the most claimant-friendly countries, such as the United States.

> **“A particularly attractive feature for patent holders is the speed of the UPC.**

A SUCCESSFUL START AND FIRST KEY CASES

Within nine months of its opening, more than 200 cases were filed with the UPC, including over 80 infringement actions, upwards of 25 revocation actions, and at least 10 applications for provisional measures, *i.e.*, preliminary injunctions. Most cases have been filed in Munich, followed by Paris and Düsseldorf.

The new option to obtain injunctions not only quickly, but for a large European territory and before commencing any infringement action, makes the UPC a particularly compelling option for patent holders. Early decisions are instructive, and show that the UPC is prepared to reward plaintiffs who present a strong case with swift and well-founded decisions. In *myStromer AG v Revolt Zycling AG*, for example, the UPC issued an *ex parte* injunction within a couple of hours.

On the same day as sending a cease-and-desist letter to Revolt Zycling, myStromer filed for a preliminary injunction against the alleged infringer. Revolt Zycling then filed a protective letter with the UPC, arguing that it had not infringed the patent. Without giving Revolt Zycling the opportunity to add to the arguments put forward in the protective letter, the Düsseldorf Local Division granted the preliminary injunction with immediate effect and within just a few hours.

In *10X Genomics, Inc. v NanoString Technologies, Inc.*, although in the first instance the Munich Local Division granted a preliminary injunction after an oral hearing in September 2023 on the basis that there was “sufficient certainty” that NanoString had infringed the asserted patent claims, and that these claims were valid, in February 2024 the Court of Appeal overturned that decision. Contrary to the Local Division’s assessment the Court of Appeal found there was no sufficient likelihood of the patent being found valid in the main proceedings (due to a lack of inventive step), and thus allowed NanoString to return to most European markets.

SETTING UNIFORM STANDARDS

In *Genomics v NanoString*, the Court of Appeal clarified important issues around the standards for claim construction, evaluating inventive step, and granting a preliminary injunction.

Specifically, the Court emphasised that – in accordance with what is known from well-established European case law – the patent claims are the starting point and decisive basis for determining the scope of patent protection. While claim construction should always consider the patent specification and drawings, there will be no protection for what is disclosed only in the specification or drawings without any basis in the patent claims.

Regarding the assessment of inventive step, the Court of Appeal showed flexibility, which is one of the core principles of the new UPC, and did not strictly apply a “problem-solution approach” as commonly practiced at the European Patent Office.

Finally, the Court of Appeal confirmed the standard for granting a preliminary injunction: it must be “more likely than not” that, firstly, the asserted patent is infringed and, secondly, the patent will be found to be valid in the main proceedings. A sufficient degree of certainty is therefore required in both infringement and revocation proceedings.

With this first landmark decision in appeal proceedings, the UPC Court of Appeal has increased legal certainty in both infringement and revocation proceedings. It has also demonstrated that it is committed to actively guiding the development of UPC law and patent practice throughout the UPC territory, ensuring the necessary flexibility.

BE PREPARED

If they haven’t already done so, companies with business activities in Europe should prepare for the impact of this important transformation of the European patent landscape. This begins with

- The strategic decision of whether or not to opt patents out of the UPC system
- The need for (strong) protective letters in cases where there is concern that an application for provisional measures will be made against them
- A well-founded case in both infringement and revocation proceedings
- Anticipation of short deadlines in UPC proceedings

A cross-border McDermott intellectual property team from Germany, the United States, France, and the United Kingdom is representing e-cigarette and premium vaping products manufacturer NJOY in nine pending revocation actions before the UPC’s Central Division in Paris, cumulatively one of the largest actions at the UPC.

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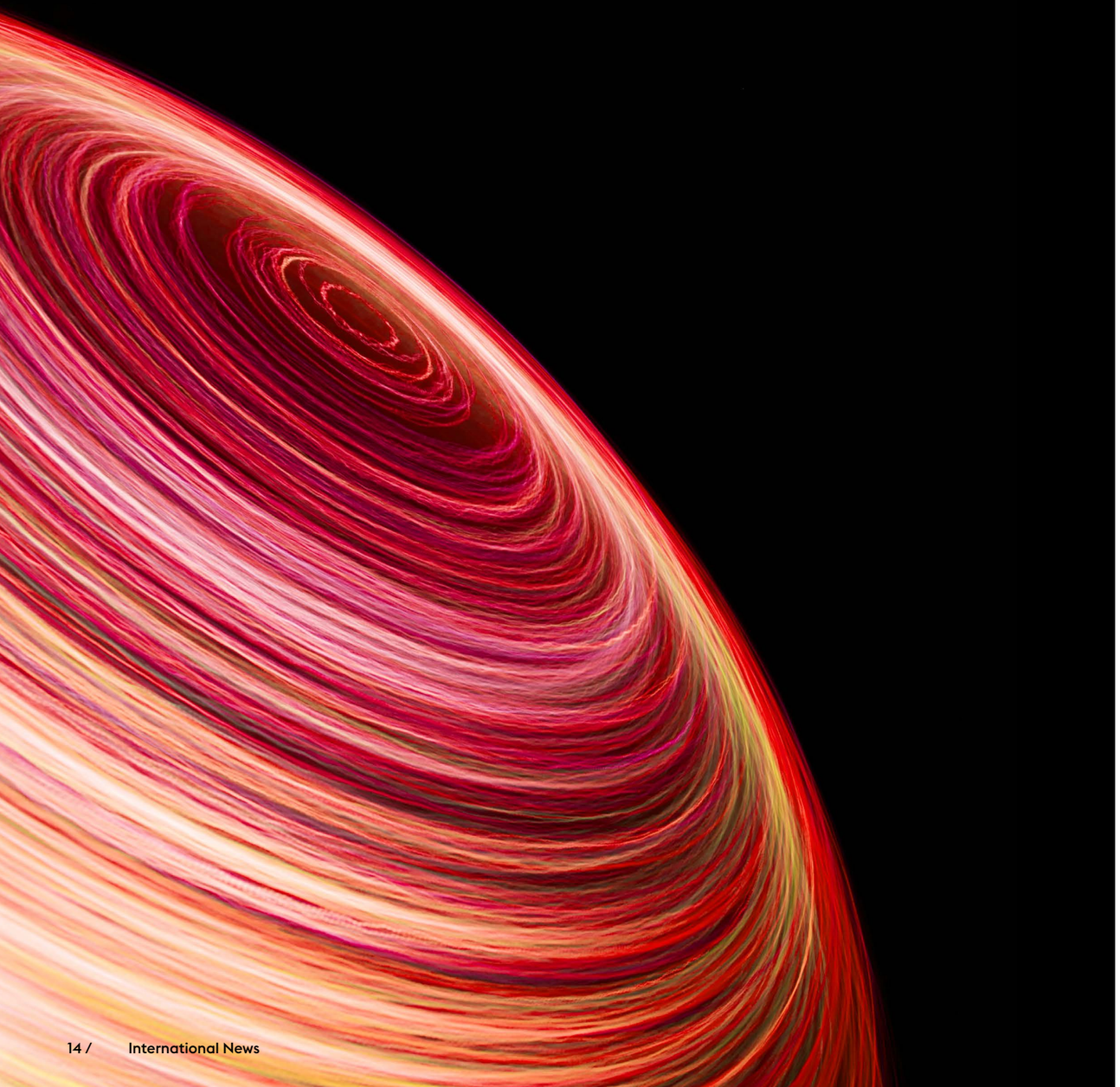
INNOVATION IN DIGITAL LEGAL SOLUTIONS

Hunter Jackson, Michael Shea, Ben Thompson and Dr Philip Uecker

From artificial intelligence (AI) and machine learning, to digital client engagement and collaboration, the legal landscape is being reshaped by innovation.



Despite traditionally being seen as the diametric opposite of innovative, the legal industry has undergone a significant digital transformation in recent years, with the emergence of new technologies and solutions that are changing the way legal services are delivered.

ARTIFICIAL INTELLIGENCE

2024 is likely to be the year when generative pre-trained transformer (GPT) technology has a major impact on the legal industry, as established technology vendors like Microsoft, and major legal research providers like Thomson Reuters and Lexis Nexis have started licensing generative AI (GenAI) platforms specifically to law firms, claiming it will help with "drafting, reviewing, and analysing contracts, documents, and data."

These providers are promoting GenAI offerings that are free from "hallucinations," which occur when the AI erroneously creates a pattern, or latches on to faults in the dataset, and creates nonsense text. "Hallucination-free" platforms are achieved through proprietary GPT models that are trained on large and structured datasets of legal documents, such as statutes, case law, and regulations.

Microsoft Co-Pilot is likely to become the main interface for law firms accessing GPT services because of the widespread use of Microsoft Office. Lawyers are expected to use it to increase efficiency, *e.g.*, summarising action items from meetings, and producing a helpful first draft that the lawyer can revise, rather than starting with a blank sheet of paper. At the moment, however, Co-Pilot is extremely expensive so is unlikely to see widespread use immediately.

Case-specific GPT models, tailored for discrete practice groups, industries, tasks, and scenarios are also being developed. These will combine information from various sources with custom GPT models that are trained on specialised datasets and objectives. For example, a GPT model will be able to perform big data analysis on financial agreements, such as those available on the US Securities and Exchange Commission's EDGAR database, to provide statistics and insights on when and how certain clauses are used. Others will be able to assist with eDiscovery by identifying and extracting relevant information from large collections of documents.

To fulfill this need, McDermott's Knowledge Management team developed Form Finder, which uses a proprietary AI search system to analyse draft agreements received from opposing parties, instantly compare them to similar agreements composed by McDermott, and determine if we have ever negotiated the same type of agreement before. Being able to identify model terms and agreements and understand the rationale behind the selection of certain clauses enables our attorneys to serve our clients efficiently and cost-effectively. Form Finder led to our being named Tech-Enabled Corp Department of the Year at *Legalweek*'s Leaders in Tech Law Awards 2023.

Before Attorneys' Liability Assurance Society (ALAS) and law firm general counsel will allow the use of GPT technology platforms, external research providers will need to implement strict quality control and verification mechanisms that include human review, peer review, and automated checks.

The use of GPT technology also poses new ethical, legal, and social implications, such as the ownership, authorship, and liability of the generated content, the privacy and security of the data, and the impact on the legal profession and the public interest. These implications require careful consideration and regulation by law firms and stakeholders, such as bar associations, courts, and clients.

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> "The use of GPT technology also poses new ethical, legal, and social implications.

DIGITAL COLLABORATION WITH CLIENTS

Another significant change benefiting the way attorneys and other legal professionals collaborate amongst themselves and with their clients results from the great variety of "virtual" platforms and tools that enable seamless communication across different locations and time zones. Ensuring that everyone has access to the same data and up-to-date information allows law firms, their clients, and other stakeholders to remain on top of the status of their matters, track outstanding tasks and deadlines, and work more effectively than before.

These tools also add value to the relationship between client and law firm by providing visibility into task planning and deadline management, often through a simplified dashboard view, putting names and faces of attorneys front and centre for clients. Firms using digital collaboration tools are offering an invaluable mechanism to save clients the time it normally takes to find the information they need to do their jobs, and making that information available in a single location across topics or matters.

> **"Firms using digital collaboration tools are offering an invaluable mechanism .**

McDermott Access is just one of the solutions McDermott has developed to facilitate digital collaboration with our clients. McDermott Access is a secure online portal that gives clients access to information and materials related to their matters and streamlines communications between a client and their legal team. The platform also provides updates on relevant news, gives clients access to digital solutions created by our attorneys, and shares insight into McDermott events and thought leadership materials.

EMPOWERING CLIENTS

Law firms and their clients also experience the benefit of greater efficiency in the delivery of legal services when innovative solutions are introduced to the practice of law. McDermott offers a variety of digital-backed solutions to our clients that add value to their operations. These offerings include "old school" technology designed to make business-as-usual processes more efficient and accurate, along with "disruptive" solutions that change how legal services are rendered and give clients new ways to gather useful insights across their organisation.

Self-service tools are a prime example of innovation that empowers legal departments to harness best-in-class forms or legal expertise to perform routine legal tasks. McDermott has developed two self-service compliance tools, Check of Regulatory Authorisations (CORA) by McDermott, and McDermott Freelancer Compliance Check, to help clients determine if their business activities are in accordance with regulatory requirements and trigger automated workflows according to the compliance survey results.

We have also developed McDermott Blueprint, a bespoke tool for McDermott clients using document assembly technology to create documents commonly used in the healthcare arena based on standard templates. The workflow includes a questionnaire that, when completed, feeds information directly to the underlying document, reducing the need to perform manual edits in a template. This has generated considerable time savings for lawyers, which directly translates to cost savings for clients.

SUPPORTING CLIENTS

We use legal technology to not only perform work on behalf of our clients, but to enhance our service delivery experience and forge strong, lasting partnerships backed by our expertise in many areas of law. Because we understand that our clients often have more work than they can effectively handle, we have developed digital solutions that enable us to help clients reduce this workload and concentrate on more valuable activities, like growing their businesses and servicing their customers. We address many common pain points by increasing efficiency and contributing to the application of consistent legal services across their organisation.

We are also available to clients who want advice on using legal technology, and help design creative solutions that augment and enhance the capabilities of their internal legal departments and other business stakeholders. As our catalogue of digital solutions continues to grow, these innovative tools will continue to make our firm and our clients more productive and efficient.

McDERMOTT'S CREATIVE DIGITAL SOLUTIONS

- McDermott Access: It's all about collaboration. Our online portal enables clients to see the status of their matters in real time and work virtually with their McDermott team. Clients can also engage with our wealth of thought leadership materials and digital services.
- Discovery: It's all about innovation. We utilise advanced technology to review and manage clients' electronically stored information more affordably, accurately, and efficiently than traditional providers.
- Quantum Tracker: It's all about transparency. Our proprietary software enables real-time budget management that tracks and evaluates projected spend, minimising any budgetary surprises.

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ARTIFICIAL INTELLIGENCE LAW CENTER

You've heard the hype around artificial intelligence (AI), now it's time to consider the practical realities. As the new technology becomes adopted in more and more industries, it is important to understand the legal implications of the use of AI.

Our cross-practice team closely monitors the evolution and continued development of AI, including the legal implications and business impacts. Our AI Law resource center is constantly updated with the latest information and insights.

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