

IP Federation

# REVIEW

Improving the Intellectual property framework to meet the needs of Innovative Industry



2025/26

2025 EDITION



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## PRESIDENT'S INTRODUCTION



I feel honoured to be writing the introduction to the 2025 IP Federation Review as the current President of the IP Federation. The IP Federation relies heavily on volunteers from member companies, and these volunteers continue to impress me with their experience and knowledge of IP matters, their understanding of the practical impact IP policy has on business, and the way members from diverse industries can come together to discuss topics to arrive at well thought out, useful policy positions, even on topics where there are diverse viewpoints in our membership. To lead such a tremendous organisation is a real privilege, and I want to take this opportunity to thank everyone involved in the IP Federation for their support.

At the start of my presidency, I set out two priorities: (1) to continue to improve our engagement and profile externally, and (2) to improve our collaboration internally. This Review showcases how we set off with a flying start, following through on these priorities. I focus on a few past and future engagements here, but these and many more are highlighted in more detail in this Review.

From an external engagement perspective, we have formed new collaborations and built upon existing ones. For a long time, we have had a good relationship with CIPA, but this year has seen us really build on this. We have also started to work together with other organisations such as ICC UK and INTA. We jointly produced a report with the ICC UK and CIPA on why patents are essential for innovation and growth and presented this during an ICC UK delegation to the WTO and WIPO. We will continue this collaboration in 2026 to ensure that the positive impact of a high-quality IP system is understood in the lead up to the WTO's 14<sup>th</sup> Ministerial Conference (MC14). We are also happy to have signed a collaboration agreement with INTA to support the organisation of the INTA annual meeting in London 2026. We are looking forward to having a strong presence at the event and engaging with officials, colleagues, and similar organisations.

With responses to three UK consultations in 2025, we made a strong start to engaging with government officials. We will continue to actively engage with key stakeholders on the topics of copyright and AI, the UK design framework and standard essential patents (SEPs).

AI tools are increasingly a part of modern innovative industry and help to improve and drive innovation. We understand the concerns of rights holders in the creative industry, and we want to ensure that the right balance is achieved between protecting rights holders and legal certainty for business to utilise AI for innovation.



On the unregistered designs front, we will continue to promote our position that criminal sanctions are wholly unsuitable for unregistered designs because of the complexity of knowing what is protected by an unregistered design and indeed whether it is protected at all. We are also looking forward to engaging in relation to standard essential patents once we receive the outcome of the consultation, which is currently expected mid-2026.

In terms of the second priority of internal collaboration, our diversity, equity and inclusion (DEI) committee has been taking the lead on this. Members of our DEI committee have been joining other committees to explore what we can be doing as IP Federation to ensure fairness at all levels in our profession. We are keen to ensure that business continues to have a strong talent pool to call upon which also means promoting STEM topics to young people and ensuring accessibility to our profession. We will continue this work into 2026 and are already supporting IP Reg with their education review which is due to open for consultation in 2026.

As mentioned, this Review highlights some of IP Federation's achievements in 2025, but takes a different tack from previous years. For those of you who are familiar with our past annual Reviews, you will notice a shift in style and content. We have taken a new approach this year to give you snapshot of our engagements in 2025, split into topic areas, as well as providing some quick read articles to give you more of an industry perspective - for which I would like to thank our contributors, in particular our guest contributors: Andrea Brewster from IP Inclusive and Jodie Albutt from Quell Therapeutics.

I hope you enjoy reading our new-style Review as much as I have enjoyed being a part of IP Federation activities. We certainly have a lot to be proud of, as you will see from the content of this Review, and we look forward to continuing to collaborate with similar organisations, and engaging with government bodies and international organisations.

Sarah Vaughan  
President, IP Federation

## 2025 SNAPSHOTS

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### **A Year of Quiet Upheaval in UK IP Policy**

2025 was a year of subtle, but potentially significant, shifts in IP in the UK. After the change of government in 2024, expectations ran high for bold reforms - yet the government's approach was more nuanced.

The launch of the government's growth-centred Modern Industrial Strategy, born from its consultation in 2024, trumpeted "innovation" nearly 200 times across its 150 pages - yet intellectual property rights were mentioned but a handful of times. This disconnect did not go unnoticed by those involved in innovation, including the IP Federation which stressed the importance of a robust and balanced IPR system to support and protect UK innovation in its consultation response.

But 2025 was far from quiet. Responses were due to the copyright and AI consultation in early 2025, and the UK Intellectual Property Office launched an impressive further 2 major consultations - on design rights reform and standard essential patents (SEPs) - with the IP Federation actively responding and engaging in each debate.

In the copyright and AI consultation, the IP Federation championed a broad text and data mining exception for commercial use - crucial for the UK's nascent AI industry - while advocating for an internationally-aligned opt-out mechanism (similar to the direction taken by the EU). The IP Federation also joined a number of stakeholder roundtables set up by the government on this issue, as well as more detailed working groups. A government reshuffle, however, put a pause on this important topic for much of the latter part of 2025.

The SEPs consultation saw the IP Federation advocate for improving transparency, education and alternative dispute resolution, even as its members' views diverged on some other aspects.

Meanwhile the design rights consultation - long overdue in the digital age and given numerous overlapping rights - sparked fierce debate over possible criminal sanctions for unregistered design rights, which the IP Federation strongly opposed. This Review includes an excellent article from the fast moving consumer goods (FMCG) perspective outlining why criminal sanctions would be a bad idea. The IP Federation's response supported reform, including having a 2-stage examination and clearer coverage of graphical user interfaces and animated designs.

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### **Global Headwinds and the Battle for Multilateralism in Global IP Policy**

If 2025 had a global theme, some might say that it was the struggle to keep multilateralism alive. While the world may seem increasingly politically disinclined in this direction, it is not in the interest of business. Multilateral agreements help harmonise rules across jurisdictions, enabling business to be conducted more easily and with greater confidence. This is particularly so in the field of intellectual property rights.

The IP Federation, undeterred, doubled down on its support for the multilateral IP order, even as Brexit realities forced a pivot toward new bilateral trade agreements. On the bilateral side, the IP Federation has worked closely with the Department of Business and Trade (DBT) to support the UK's Free Trade Agreement negotiations, to ensure that the IP chapters are sufficiently robust. Internationally, the IP

Federation's advocacy extended from WTO and WIPO meetings in Geneva to hands-on support for the UK's free trade agreement with India and engagement with officials from emerging markets like Uzbekistan, who were interested to hear from industry how IP works in practice.

Nevertheless, the spectre continues to loom of a weakening of IP and innovation, either through agreements relating to the environment or through weakening of the TRIPS agreement, especially with the upcoming WTO's Ministerial Conference (MC14) on the horizon. With this concern in mind, the IP Federation, alongside the ICC UK and CIPA, worked effectively to present a positive perspective of IP, using real-world case studies to convince diplomats and policymakers on the role of multilateral organisations in supporting innovation, intellectual property and global trade. You can find a copy of our joint case studies here:

- [Why patents are essential for innovation and growth](#)
- [Patents as engines of growth](#)

We also hosted the UK IPO's international IP attachés in London and further expressed the need for UK government support for IP internationally in our response to the new government's then forthcoming trade strategy.

And closer to home, the IP Federation explored what opportunities may exist for a warmer relationship with the EU through our continued participation in the UK Domestic Advisory Group and we were pleased to see December's announcement that the UK will rejoin the Erasmus+ programme from 2027. We also sat down with EPO President, António Campinos and Vice-President, Steve Rowan, for a candid exchange on the EPO's latest reforms. Representing some of the largest patent filers, IP Federation members offered incisive insights and feedback.

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## Courts, Controversies and the Power of Intervention

The IP Federation's impact was felt not just in policy circles, but in the courts. In a landmark case, the IP Federation challenged the UPC Court of First Instance (CFI)'s decision in *Suinno v Microsoft*. In this case, the CFI had concluded that an employee of a company, even if sufficiently qualified, could not act as the company's representative before the UPC because, according to the CFI, they were not independent in accordance with the rules of the UPC. The IP Federation's position is that in-house lawyers and attorneys should have the same rights as private practice lawyers, whether it is in the area of privilege or rights of representation.

Although not procedurally possible for the IP Federation to intervene formally in the case, it wrote to the UPC Court of Appeal's Presiding Judge - Judge Grabinski - expressing its concern with the CFI's decision. The letter - and CIPA's - attracted wide press coverage. The Court of Appeal's subsequent reversal of the CFI's decision aligned with the IP Federation's and CIPA's submission, confirming that an employee of a company could represent its employer if it did so independently.

The case also exposed a glaring omission in the UPC's rules: interested third parties face real hurdles when trying to present arguments and evidence to the CoA on issues that matter to a decision, but are not being argued by the parties. It is a gap that requires consideration in any future change to the rules.

Elsewhere, the IP Federation joined forces with CIPA in a high-profile intervention before the UK's Supreme Court in the *Emotional Perception AI* case, which related to the patentability of an artificial neural network that recommends media files. Given that the Supreme Court's decision could redefine the patentability of AI-driven inventions, the IP Federation chose to intervene. In its intervention, cited repeatedly

during the hearing, the IP Federation expressed the importance of clarity and consistency in the assessment of computer-implemented inventions. The intervention appears to have had a clear impact on the Supreme Court, where it was specifically referred to by Lord Briggs at the beginning and end of the hearing. At the time of writing, the Supreme Court's decision in this case remains pending. Something to look forward to in 2026.

In addition to engaging in court proceedings, two decisions of the EPO's Enlarged Board of Appeal in 2025 (G 1/23 and G 1/24) aligned with the arguments presented by the IP Federation in its amicus briefs submitted to the Board - nicely notching up a couple more successes in 2025.

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## Championing Inclusion Amidst Change

2025 was a challenging year for diversity, equity and inclusion (DEI). Nevertheless, the IP Federation remained a steadfast supporter of DEI initiatives, including IP Inclusive, In2scienceUK and Physics Partners. How organisations are managing the current realities is well illustrated in our guest article by IP Inclusive's Andrea Brewster OBE.

As Andrea reports, IP Inclusive celebrated its 10th anniversary in 2025. This included a panel discussion on *"why do diversity & inclusion still matter?"*, which was joined by IP Federation's then President, Adrian Howes. This followed another excellent event from the European Diversity, Equity and Inclusion IP Forum 2025, organised by IP Inclusive, at which IP Federation's DEI Chair, Alex Driver, led a panel discussion.

While celebrating its 10th anniversary this year, IP Inclusive also launched its [in-house senior leaders' pledge](#) - an evolution from the original version designed for private practice IP departments. While its predecessor has received over a hundred signatures, there are, as at the time of writing, only 4 in-house signatories so far. Therefore, please show your support to inclusivity by signing up if you are in-house. Now, more than ever, it is important for the IP world to lead the way here.

In this regard, the IP Federation has also supported efforts by CIPA and many others, in particular its former President and 2025 CIPA President, Bobby Mukherjee, in developing a paralegal and patent attorney apprenticeship scheme. This scheme would create new structured vocational pathways into the IP profession. It is being designed to open the profession to a broader, more diverse talent pool, recognising that the future of IP depends on inclusion to innovate.

## LONGER READS

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### Patents supporting innovation: A Rolls-Royce case study



Everyone is on a journey towards net zero, yet our desire to travel by aeroplane is growing, so we need technology to deliver a solution. The [International Civil Aviation Organisation \(ICAO\)](#) predicts that the impact of increased flying hours can be significantly mitigated by the use of new technologies, and that combining new technologies with alternative fuels can reduce CO2 emissions in 2050 compared to current levels, despite the predicted increase in demand. Rolls-Royce is investing in both the use of alternative fuels and new technology. Rolls-Royce's [UltraFan®](#) engine hosts a suite of new technologies and boasts a 25% fuel burn improvement compared to Rolls-Royce's first generation Trent engines. The ability to develop and deliver on so many new technologies is in part due to the way we are able to collaborate with our extensive network of Universities, Research centres and other partners. We are able to rely on a high-quality IP Framework in the UK (and other countries) to help to foster and enhance our relationships with these external bodies.

There are a suite of technologies that make the UltraFan engine more efficient, but there is also a set change in architecture compared to the Trent engines. In a gas turbine engine there is a fan, compressor section (with multiple compressors), combustor and turbine section (with multiple turbines). The traditional Trent engine family had three turbines, one directly driving the fan and the other two directly driving the compressors. The UltraFan is different, instead of having a dedicated turbine to drive the fan, a gearbox is used so that a turbine drives both a compressor and the fan. By decoupling the turbine from the fan using a gearbox, the speed of the fan and the speed of the turbine can be optimised, bringing efficiency savings. Efficiency is also increased by the new ability to have a much larger diameter fan.

A fan is made up of multiple fan blades, on the UltraFan these blades are much bigger than comparable Trent engines. The fan will also be made from composite materials with a titanium leading edge, instead of our more common choice of fully titanium. Due to their large size, the composite fan blades need reinforcing so that they can withstand events such as a bird strike.

Our journey to developing an automated manufacturing method for reinforcing

composite fan blades started with Rolls-Royce funded research work at the [University of Bristol](#), who Rolls-Royce have been partnering with for over 15 years. The research work included sponsoring several PhD Theses. The involvement of the University of Bristol has supported the education of multiple students and enabled the University of Bristol to build up experience and capability for innovative development at the highest level.

The work initiated at the University of Bristol has resulted in a new Direct Insertion manufacturing method for through-thickness reinforcement (TTR) of composite fan blades. The composite fan blades are made up of layers of carbon fibres in a resin matrix, the direction of the carbon fibres varies between layers to optimise performance of the blade. TTR inserts pre-cured carbon fibre rods into the composite layers. This method has been found to improve the performance of composites with fewer process induced defects than other methods.

Once this initial concept was conceived, Rolls-Royce was able to patent the solution. This enabled Rolls-Royce to proceed with the development of the technology in the comfort that they had the underlying technology protected so they could continue to effectively collaborate to develop the technology further, whilst also permitting the University of Bristol to publish their work.

Once the baseline concept had been developed at the University, the technology needed to be industrialised to a level that could be used in a manufacturing process. This work was done at the [NCC](#) (formerly known as the National Composites Centre), where Rolls-Royce was one of the founding members. The NCC's website explains that they "bridge the gap between academia and industry, helping companies of every size to capitalise on cutting-edge innovation to deliver more." The NCC "provide businesses access to £300m state-of-the-art innovation facilities, engineering expertise and leading research".

NCC and Rolls-Royce were able to work together closely to develop the technology; both parties being comfortable collaborating because IP protections were in place via contracts and the filed patent. Additional patents were filed relating to the technology, again reaching a balance between Rolls-Royce's commercial interests and that of research bodies to publish the work they are doing, which in turn contributes to the furthering of knowledge in the industry.

The method developed initially at the University of Bristol, then further developed at the NCC has now become our baseline design and Rolls-Royce are testing it at their preproduction facility in Bristol.

There are numerous examples of technologies on Rolls-Royce's engines which have originated in a university, highlighting how valuable these relationships are for both Rolls-Royce, universities and advanced capability research centres (such as the NCC). A high-quality IP framework means that patents can be filed to protect inventions, and know-how can be shared with protection from meaningful contract agreements.

Sarah Vaughan

Senior Patent Attorney, Rolls-Royce plc

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## **Why would the FMCG industry be opposed to criminal sanctions for UK UDR infringement?**

The UK IPO has been consulting on possible changes to UK design law. One of those changes concerned the introduction of criminal sanctions for the infringement of UK unregistered design rights (UDR). The IP Federation strongly opposes such an introduction. The following article focuses on how the fast moving consumer goods (FMCG) industry would be impacted and why it is opposed thereto.

The FMCG industry faces a confluence of challenges when bringing its products to market. A non-exhaustive list of those challenges includes: rapid product innovation cycles; managing the relationship with retailers (including battle for shelf-space / avoiding supply disruption); supply chain complexity; rising raw material costs; relationship with end consumers; brand equity preservation and growth; targeting of high profile brands for vexatious litigation; management bandwidth; etc.

The challenges mentioned above are not exclusive to FMCG; they will be felt across various industry sectors. However, their impact within FMCG has promoted a necessity for early and accurate assessment of freedom to operate (FTO) risks for all new product launches.

When conducting design FTO searching for a new product design, account must be taken of both registered designs and unregistered designs. There are numerous database searching tools that can facilitate the searching of registered designs. The register entry for each design can be inspected to understand its validity and scope to arrive at a FTO risk assessment for the new product.

However, it is more challenging to conduct FTO of unregistered design rights (UDR) due to how those rights come into existence. UDR are rights that come into existence automatically and for free if the qualification requirements are met and, importantly, with no obligation to register or publish their existence. As a consequence, their existence, scope and validity are untested and opaque.

Since it is not possible to determine whether a potentially conflicting UDR exists, its validity, what it protects, or for how long, guardrails are put in place to avoid infringing UDR. One commonly used guardrail is contractual. FMCG companies often use external design agencies for their product design endeavours, and it is possible to contractually require that those design agencies warrant that they will not copy an existing design and indemnify the FMCG company in cases where there is an allegation of copying an existing design that is protected by UDR. Those contractual guardrails work well when civil remedies are the sole recourse for dealing with infringement, but they are unlikely to work should criminal prosecutions be available.

Compounding the difficulties associated with criminalisation of UDR infringement is that the UK criminal courts and criminal enforcement mechanisms are wholly unsuited to deal with matters of UDR infringement, as the legal certainty of the allegedly infringed UDR is almost always going to be in question insofar as its validity and scope are concerned. Criminal courts have no experience in dealing with a determination of whether a UDR exists, the extent to which it is valid and whether the alleged infringement actually infringes, which results in significant uncertainty for both the court and potential defendants.

FMCG product design is typically iterative rather than truly innovative. If criminal sanctions were to be extended to UDR, it would necessarily increase the FTO risk profile for products bearing new designs, particularly iterative designs, as the existing safeguards for avoiding UDR infringement would no longer be sufficient when the impacts of getting it wrong could result in criminal prosecution.

In a post-criminalisation of UDR environment, FMCG companies would increasingly pursue the low-risk approach of reusing old product designs that have a track record of being free from UDR infringement risks. The fear of criminal sanctions, no matter how remote, would result in the stifling of the design industry within the FMCG industry, as companies would elect to dramatically reduce efforts to innovate in product design; the unknown and unquantifiable risk would not be worth the reward.

Robert Carlin  
Chair of the IP Federation Design Committee  
In-house Patent Attorney

**Guest article****Changing tides on the DEI coastline  
(and why IP Inclusive matters more now than ever)**

My heart sank when the anti-woke rhetoric began. Was this the end of the drive for diversity, equity and inclusion (DEI)? Was it to be just a passing fad? Would IP Inclusive be left by the wayside, just as it reached its tenth anniversary year?

Regime changes in the US stoked the fires of protectionism that were already smouldering across the UK and Europe. At best these developments provided a convenient excuse, for governments and companies already grappling with an economic downturn, to cut their DEI budgets. At worst, some began to normalise, and broaden, discrimination between the In-Crowd and the Others.

But if I was afraid, how much more so were the people IP Inclusive supported?

We spent our anniversary year talking to IP folk about how the changes were affecting them and their businesses. And something interesting emerged. Many businesses *did* still care about DEI. They might be changing the way they talked about it, but they could still see the value of a diverse workforce, an inclusive and supportive environment, and people management based on equity and respect.

More important even than that, individual professionals still cared. In organisations dialling down their DEI efforts, staff were not happy - and ultimately, in terms of talent recruitment and retention, that would create a strong business case for dialling up again.

We realised that, far from fading away, IP Inclusive was more important now than ever. Apolitical and set apart from individual businesses, it could champion causes that others found difficult to address in public, speak up for individuals whose companies had stepped back from DEI. It was a crucial safe space where people from across the sector could collaborate without judgement, where allyship provided safety in numbers and both amplified and focussed individual contributions.

We began to understand the power of the IP Inclusive community. Both the cause and the manifestation of our success thus far, this was what we should be focussing on as we weathered the anti-DEI storm. When we wrote our 2025-27 business plan, “community” was its underlying theme.

I’ve spoken to people in companies that still “walk the walk”. They feel proud, secure and valued. I’ve also spoken to those in the opposite situation, who feel let down, maybe scared, and also exasperated - because so much of what was done under the DEI banner had made their workplaces better, and now it was being thrown away. Some of those people will doubtless be looking to move.

Through IP Inclusive, though, they can still find friendship, support and reassurance. Our six communities are especially important for this, but more widely, IP Inclusive can keep the difficult conversations going, lobby for change, support representative bodies and regulators who also want to incentivise DEI. We can offer ideas, guidance and resources that help people make a case for DEI back in their own organisations. And we can share best practices that they can adopt for themselves even if not through their corporate policies.

We can also continue the push for a wider pipeline of recruits. Our [Careers in Ideas](#) campaign, which focusses on access to the professions and expanding the talent pool, provides a hook into wider “corporate social responsibility”- and community-focussed work that can be easier to justify than individual efforts to improve diversity.

I appreciate that what's happening on the DEI front presents greater risks for large companies and for those with a global reach, in particular where they depend on overseas contracts. For the people who work there, IP Inclusive can provide the support networks, discussions and resources that their employers cannot. A relatively small IP team in a big corporation may have little influence on their company's DEI policies, and less autonomy in DEI-related activities; we can give them more options.

So, at the end of IP Inclusive's first decade, as the outside world becomes more hostile - or at least trickier to navigate - the case for us to continue is actually stronger than ever. And I believe we're well placed to respond. Our unique pan-professional but sector-specific approach remains a core strength, as does our focus on general inclusivity rather than individual diversity stats, and our intersectional approach that allows everyone to get involved, whether as allies or as members of the classic diversity groups.

I'm glad we called ourselves IP "Inclusive". The word "diversity" triggers discord, whereas even now, the general concepts of inclusivity and belonging still seem palatable. And yet, let's be clear, *diversity* is still our ultimate goal. Diverse perspectives make for better decisions. Diverse inputs create more innovative teams and more agile responses. We need to stand firm on this. Diversity will make our businesses stronger, more successful, more sustainable. We do this for individual IP professionals, the businesses they work in, the clients they serve, and the IP sector as a whole.

To my relief, people have not stopped donating to IP Inclusive this year. They have not stopped coming to our events, and at those events they are still saying that DEI matters. Our recent panel discussion on ["The case for EDI: why we need to continue"](#), where we heard insights from across the world, yielded an overall positive message for the future.

We are part of a wonderful profession, full of broad-minded and well-intentioned people. The DEI agenda is just one way in which the UK IP sector can continue to shine. IP Inclusive stands ready to help with that. We face our second decade, ironically perhaps in view of the conditions outside, with greater confidence, a stronger sense of purpose and a more loyal community of supporters than ever.

Andrea Brewster  
Lead Executive Officer, IP Inclusive

**Guest article****IP considerations for early stage biotech – Quell Therapeutics**

In 2025 the award of the Physiology or Medicine Nobel Prize went to Mary Brunkow, Fred Ramsdell and Shimon Sakaguchi for the discovery of T regulatory cells and their mechanisms of action. Quell Therapeutics is at the heart of this revolution in medicine.

***Background***

Quell is a London-based biotech company advancing engineered T regulatory cell therapies for the treatment of severe immune disorders. The company was founded in 2019, at a time when the engineered T regulatory cell field was largely academic and preclinical, with only a handful of companies working in the area. This early stage environment offered a unique opportunity for innovation and filing intellectual property (IP) that had the potential to provide the company with a commercial advantage as the industry matured.

Quell had a strong focus on patent protection from the outset. Its early investment in expertise demonstrated the commitment of our investors and the senior management team to IP, and the ability to obtain patent protection was a key driver in the selection of our initial product. Although early-stage companies are often founded on research from universities, and therefore may have some initial in-licensed IP, early resource spend on building out the patent portfolio, such as that committed by Quell, can result in multiple benefits, including providing fall back positions for any existing IP; building trust early on with investors to provide confidence that innovation is being protected; developing a portfolio for later fund raising to meet expectations of current and new investors; and particularly in younger fields, establishing broad claims to provide product spanning IP.

***Quell's products***

Quell's products are based upon multi-modular engineered T regulatory cells, which utilise both product specific and platform technologies. Our cell products contain a chimeric antigen receptor (CAR) allowing their specific targeting to a site of disease within the body and activation of the cells upon target engagement. The CAR is a product-specific piece of technology (i.e. different CARs are used for different products/different disease conditions), usually having an extracellular domain derived from an antibody and an intracellular signalling domain. Protection of the CAR with IP typically provides protection for individual pipeline products which may be important e.g. for partnering (typically control over product-specific filings can be more easily handed over to a partner than platform filings), and which may build on any patent term which exists for earlier platform filings. However, depending on the stage of the field and prior art around the target for the CAR, it may still be possible in some territories to obtain broader protection, which can be invaluable for blocking the field more broadly and early stage companies should consider this possibility.

Quell also has a toolbox of other different modules which may be expressed within our cell products to provide different functionalities, to stabilise phenotype, or to increase persistence as necessary. Given the early stage of the field in 2019, we initially looked to develop and protect a platform technology that could beneficially be used across a range of products and which had the potential to effectively block competitors. The technology that we selected allowed the manufacture of cells with a highly stable T regulatory phenotype (as compared to cells without the technology which can have an unstable phenotype under proinflammatory conditions), enabling the production of high-quality product across our pipeline. The technology clearly

differentiates Quell from others working in the field and filing IP in relation to platform technology developments, has resulted in protection from competitors and a proprietary position which we can leverage to attract interest in our business.

### *The journey*

In early 2021, Quell had several products in its pipeline and was able to close an extended Series A financing, to circa \$84 million, with our initial investors. By this time, additional competitor companies had also been founded in the T regulatory cell field demonstrating the criticality of early IP filings for any business around its platform. In October 2021, Quell presented data showing at a conference for the first time that our proprietary platform technology was able to enhance the safety, stability and efficacy of Treg cells.

Quell was simultaneously developing a manufacturing process to enable reliable production of a high quality and high yield product, to supply our clinical trials. Being an early player in the field, meant that manufacturing processes were not well known or disclosed in the art to fit these needs. Quell's process development throughout our journey resulted in a highly optimised manufacturing process which provided the company with further opportunities to build our IP portfolio (with consideration to both patent protection and trade secrets/know how) and an advantage over our competitors.

Having an IP portfolio has proved extremely important during diligence and subsequent fund raising (\$156 million in an oversubscribed Series B) and large pharma partnering. IP has enabled Quell to develop platform technology and a manufacturing process that we can call proprietary and that differentiates our company from our competitors. Further, our product-specific IP that has been filed during development of our pipeline, builds confidence that we will have long term protection, which is important due to the extended development timelines for cell therapies.

Biotech companies need to collaborate with different third parties at different stages of their journey (CROs, CDMOs, academic institutions, investors, potential partners etc). For Quell, collaboration has been essential and we have interacted with multiple partners across different business functions during the past 6 years. Having IP protection really makes collaboration easier and enables interaction with confidence at every level, providing another reason as to how IP can work for a business before commercialisation of any products.

### *Today*

The T regulatory field is still as or maybe more exciting than it was in 2019, particularly with the recent 2025 award of the Physiology or Medicine Nobel Prize. The growing interest in the field means that IP will be as important as ever going forwards, to protect new innovation and future products to ensure investment and eventual commercialisation for the ultimate benefit of patients.

Jodie Albutt, VP, Intellectual Property,  
Quell Therapeutics Ltd

## Who pays for the use of digital sequence information (DSI)?

The Convention on Biological Diversity (CBD) (to which the Nagoya Protocol on Access and Benefit Sharing is a supplementary agreement) provides for regular Conferences of the Parties (COPs). Concerns have been expressed that the Nagoya ABS system has not raised as much revenue for the support of biodiversity as was hoped. Consequently, various parties have turned their attention to other ways to raise funds for this purpose. The most recent meetings, COP16, in Cali, Colombia, produced a Decision which creates a fund to be financed by users of digital sequence information (DSI).

What is DSI? The flora and fauna of this world all contain RNA or DNA (usually in chromosomes) which codes for, and enables expression of, proteins that makes up their structures. The RNA or DNA is, normally, made of just four differing molecules (known as bases) strung together in a sequence and each triplet of these bases codes for one of twenty amino acids which form proteins. The sequences of RNA, DNA or proteins are conventionally represented by a series of letters. This information can be found stored digitally in various online repositories and the amount of this information is increasing. Some parties to the CBD consider that industrial users of DSI thus profit from the biodiversity of the natural environment and so should provide funding to ensure its maintenance. Needless to say, if this were mandatory and wide in scope it would have potentially wide ramifications across a variety of industries, not just medicines or health care products, but also many other products such as those used in fast moving consumer goods - think shampoos or detergents which may contain enzymes derived from biological sources.

What was decided at COP16? In relation to DSI that is made publicly available, users in sectors that directly or indirectly benefit from its use in their commercial activities, should contribute to a fund if they are above a certain threshold in size (two out of three of \$20M in assets, \$50M in sales and \$5M in profits). The payments should be 0.1% of turnover or 1% of revenue. The Decision is without prejudice to national laws and it will be for each CBD party to decide whether and how to implement the Decision in its national law.

The Decision is non-binding on participants, but gives rise to many questions.

1. Is this payment voluntary or involuntary? At the end of COP16 the UK Government made public that they would treat payments as voluntary. It is not clear that this will be the view of other countries. If the payment is involuntary, is this a tax?
2. Are payments to be made on national or global turnover or profit? This is an important issue since the world's biggest economy, the USA, is not a party to the CBD. Should any country require payments on global turnover or profit this would lead to an absurd situation of double payments being required.
3. The Decision contains an 'indicative' list of sectors that are captured. This includes pharmaceuticals, nutraceuticals, cosmetics, animal and plant breeding and biotechnology. Given the list is indicative it is understood that any sector can be within scope of the Decision.
4. What is "DSI" and what does it mean to be a 'user' of DSI? The UK is considering the meaning of "DSI" in a related context. As far as a "user" is concerned, on the one hand, some companies do use DSI (however defined) in the generation of products. On the other, almost every company uses products that were made in this way in at least part of their business - are they expected to pay? Is this what is meant by the distinction between 'direct' and 'indirect' use?
5. Are payments to be made only in respect of products sold by a company that incorporate DSI? Some companies will sell both such products and products with

no link to DSI. On its face the Decision implies that if any DSI is used by a company, all of its turnover and profit is in scope.

6. What is the benefit for a company of paying into the fund? If a company pays into the fund, does that absolve it from payment obligations under national laws or analogous international mechanisms? The Decision merely provides that if a company makes a payment in line with the decision, it will receive a certificate excluding the expectation of making further payments into the fund that year. But does this also exempt users from payments under similar national schemes, or ensure that any patents for inventions utilising DSI are not vulnerable to limitation? That this is a serious concern is demonstrated by the fact that the UK, along with Chile and other like-minded countries calling themselves the Friends of the Cali Fund, is working to conclude a declaration to ensure that such payment stacking will be avoided, at least among the Friends.
7. Is human DSI in scope? It appears the answer to the question is no, since the ABS system under the Nagoya Protocol does not include human genetic resources.

Regrettably none of the preparatory material for COP16 gives clarity on the issues above or discusses where, how and to what extent DSI is used industrially. Assumptions are made that the major use of it is in the pharmaceutical industry. However most of the DSI used in that sector is from humans and much of the rest relates to pathogens which are subject to their own access and benefit sharing scheme (which is still being negotiated) if they might lead to a pandemic, or subject to an existing scheme if influenza.

Non-human DSI is mostly used in producing and testing potential treatments. For example, it may be used in generating cell lines for the production of biological therapeutics. In common with many other industries, it can also be found in the adoption 'green chemistry' which involves the generation of substrate specific enzymes from bacteria for use in synthesising pharmaceuticals to avoid high temperature energy intensive reactions and potentially harmful volatile solvents. DSI from standard laboratory animal models can also contribute to exploring the safety and efficacy of experimental drugs. All of these activities are routine and have contributed significantly to the production of revolutionary treatments. DSI is important in the commercially smaller animal health sector which is vital for the health and welfare of farm animals as well as pets, especially in treating pathogens and parasites.

A proper analysis of where and how DSI is used would likely show that many sectors rely on it in some way, and certainly almost any sector that produces physical products will be an indirect user if this term is taken at its broadest.

What is the origin of DSI in patent applications? One study (Identifying Ways Forward, LSE, 2024) showed that the origin of about 70% of sequences is not given. Many may, of course, be artificial. About 25% was of human origin. Of the rest, the top ten species was dominated by laboratory models, such as rats and mice, standard expression systems such as E. coli and yeast, staple crops such as rice, domesticated animals such as cows and botanical laboratory models. It is noteworthy how few patent applications utilise DSI from biodiverse sources. It should not be surprising that the focus of biotechnological activity has been on those species on which human existence is most dependent.

At the time of the Decision, optimism was expressed that the Cali Fund would raise billions of dollars. Uncertainty around the issues referred to above and several others may explain, at least in part, why to date only a single donation of \$1,000 has been made (and that by a company too small to fall within the scope the payment expectation). Given that many questions remain it is to be hoped that parties to the



CBD will clarify their understandings of what the Decision means. It is probably too much to expect that there will be complete consensus, but the fund is only likely to attract resources if there is a clear understanding on how the fund supports biodiversity and a harmonised and realistic approach to payments without duplication. Perhaps the efforts of the Friends of the Cali Fund will help; perhaps not.

James Horgan  
Merck Sharp & Dohme

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