Managing IP

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25th 周年紀念 ANNIVERSARY

Winter 2022

ManagingIP.com
Issue 296

Ed Conlon
Editor-in-chief

Festive 50

Much as Christmas seems to roll around faster every year, so does our list of the 50 Most Influential People in IP, a selection of which appears in the cover story of this PDF (the full version is available on our website).

The people we profile must have done something truly influential, so their inclusion is genuinely something to take note of. It's never an easy task sifting through and agreeing on all the names, but it's always a team effort and it really gets us thinking. The full list is split into five categories – judges; IP authorities; industry leaders; notable individuals; and public officials – and includes a profile for each entry.

It would be impossible to sum up the IP highlights of 2022 in one paragraph, but if one thing stood out, it would probably be the long-running campaign seeking to affirm that artificial intelligence program DABUS should be named as an inventor on numerous patent applications. Computer scientist Stephen Thaler and his backers at the Artificial Inventorship Project have so far failed at every hurdle bar one – in Australia, where the top court later reversed an earlier ruling in the project's favour anyway. Another appeal by Thaler and co will be heard by the UK Supreme Court in March 2023, and it will be intriguing to see what the outcome is.

As we head into next year, the other biggest issue in IP is undoubtedly the Unified Patent Court (UPC), which finally looks set to launch in the spring. Despite being years in the making, the court has been beset by technical difficulties even before it has begun, with users being mostly unable to access the all-important case management system and electronic signing platform. The opening of the court has now been delayed until June, while the sunrise period is due to launch on March 1, two months later than planned. It's going to be a tough start to the year for the UPC organisers, for sure.

In trademarks, one of the hot topics is not what, but who. As we reported in November, incumbent executive director of the EUIPO, Christian Archambeau, surprisingly failed to win a nomination for a second term, meaning he will depart by September 2023. The office hopes to have picked a successor by June, so we should have an idea of their identity by the summer. There are plenty of possible replacements, including any of the heads of the leading national IP offices in Europe, and speculation will almost certainly begin to mount going into next year.

With that, we wish you a merry Christmas and happy new year; see you in 2023.

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ISSN 0960-5002
Managing IP is published 4 times a year for $2,980 per year by Euromoney Trading Limited.

The top 50 influential people in IP

It's that time of year again – we profile a selection of the people who left a mark on the IP sector this year

Prathiba Singh, judge, Delhi High Court

Justice Prathiba Singh made last year's list because of her instrumental role in setting up India's first intellectual property-focused judicial forum, the Delhi High Court Intellectual Property Division.

This year, she was picked for handing down some excellent rulings as one of the first appointed judges of the newly established forum.

According to stakeholders, Singh hasn't just been using judgments to resolve individual cases, she has also set out broad policy positions to help rights owners more generally.

In March, she took the IP office to task when she fined two officers for failing to disclose material facts in *Dr Reddy's Laboratories v Controller General of Patents Designs and Trademarks*.

She also directed the IP office to formulate a plan to deal with the more than 200,000 oppositions pending before it.

In *Dabur India v Ashok Kumar*, she directed government authorities, ICANN, and domain name registrars to formulate solutions to curb malpractice from registrants.

Singh was also part of the two committees that released rules on the functioning of the IP division and adjudication of patent disputes in February.

These rules have made processing IP cases, particularly patent matters, much faster and easier.

Singh has held a judicial position for a little over five years – but her record already shows that having a former industry practitioner as a judge can lead to real and effective change.

"Singh has held a judicial position for a little over five years – but her record already shows that having a former industry practitioner as a judge can lead to real and effective change."

Ngozi Okonjo-Iweala, director-general, WTO

The COVID patent waiver, proposed by India and South Africa in October 2020 at the World Trade Organization (WTO), was one of the most contested projects in the intellectual property industry last year.

Thanks to director-general Ngozi Okonjo-Iweala's consistent efforts to mediate the interests of different countries and stakeholders, however, WTO members agreed to a partial waiver of IP rights in June.

Okonjo-Iweala voiced the need to boost vaccine accessibility in developing countries shortly after she was elected to office in 2021.

The June deal temporarily removed IP barriers around COVID vaccine patents for low and middle-income countries – although it was a considerably watered-down version of what India and South Africa initially proposed.

Okonjo-Iweala said: "On the TRIPS waiver, now we have something in hand."

"It's really exciting now to go to those factories that are starting to set up all over the developing world and start to work with them."

Though many argue that the deal offers little beyond the exemptions already enjoyed by WTO members, Okonjo-Iweala's hard work to make the COVID patent waiver a reality – whether you love it or hate it – deserves recognition.

"Okonjo-Iweala voiced the need to boost vaccine accessibility in developing countries shortly after she was elected to office in 2021."

Juliette Rouilloux-Sicre, vice president of intellectual property, Thales

Juliette Rouilloux-Sicre, vice president of intellectual property at Thales, was at the heart of one of the most closely watched sagas in standard essential patent litigation this year.

The French electrical manufacturer had SEP owners worried when it argued that Philips' efforts to seek an exclusion order at the US International Trade Commission violated its commitment to license SEPs on fair, reasonable, and non-discriminatory (FRAND) terms.

Thales asked the Court of Appeals for the Federal Circuit to step in after Philips sued at the ITC and the District Court for the District of Delaware.

If the Federal Circuit had sided with Thales, it could have amounted to a ban on SEP owners seeking injunctive relief at the ITC.

Coupled with the landmark *eBay* ruling, which effectively put injunctions out of reach in SEP district court litigation, the case could have severely limited SEP owners' enforcement options.

It didn't quite turn out that way, but neither has the question been settled just yet.

The Federal Circuit declined to rule one way or the other on the SEP issue, largely because the ITC never actually issued an exclusion order.

The ambiguous ruling leaves the door open for other defendants to follow Thales's lead and pose the question again in future.

"Juliette Rouilloux-Sicre was at the heart of one of the most closely watched sagas in standard essential patent litigation this year."

Kerstin Jorna, director general for DG Grow, European Commission

The European Commission laid down a marker in the field of standard essential patents this year.

With so many plates spinning – different initiatives and policy reviews – it's rare that the EU doesn't have something of note to say on SEPs in a given year.

But the consultation on a new framework for SEPs, issued by the Directorate General for Internal Market, Industry, Entrepreneurship and SMEs (DG Grow) in February, was especially significant.

The document indicates the sorts of SEP issues that DG Grow, under the leadership of director general Kerstin Jorna, considers to be the worthiest of attention.

And in a field as contentious as SEPs, the key is identifying where the problems lie.

Patent owners, implementers, and other stakeholders each gave their own, probably contradictory, views on that question during the call for evidence between February and May.

We will know the outcome, and DG Grow's own view, by the end of the next year – but for now, the consultation documents provide some clues.

We know DG Grow is concerned with a lack of transparency in SEP licensing, including on how many patents are truly standard essential.

It's also difficult for patent owners and implementers to calculate royalty rates, as there is hardly any publicly available information on SEP deals.

That lack of transparency and common reference point only makes litigation harder to avoid.

DG Grow's willingness to tackle these issues is significant in and of itself. After all, the current US policy is not to have a policy, since the withdrawal of the Department of Justice's 2019 statement.

"Jorna, a former director of IP policy at DG Grow, is now best placed to steer the global conversation on SEPs."

Jorna, a former director of IP policy at DG Grow, is now best placed to steer the global conversation on SEPs.

Ed Sheeran, pop star

Ed Sheeran has spent more time thinking about copyright than he might have liked over the past few years.

The pop star successfully beat claims that he copied elements of his hit 'Shape of You' at the England and Wales High Court in April.

He will soon face a trial in the US over separate claims that he plagiarised Marvin Gaye's song 'Let's Get It On'.

By his own admission, he's getting fed up.

Sheeran took his 'Shape of You' win in April as an opportunity to raise the alarm on what he saw as a culture of baseless music copyright litigation.

"I feel claims like this are way too common now. This really does have to end.

"It's really damaging to the songwriting industry. There's only so many notes and very few chords used in pop music.

"Coincidence is bound to happen if 60,000 songs are being released every day on Spotify. That's 22 million songs a year, and there's only 12 notes that are available," Sheeran said.

His comments likely resonated with defendants in other high-profile copyright suits, such as Katy Perry, who dodged $2.8 million in copyright damages on appeal in March.

"Sheeran hopes his success will discourage more of what he sees as opportunistic claims designed to win quick settlements."

Sheeran hopes his success will discourage more of what he sees as opportunistic claims designed to win quick settlements.

NFTs and the metaverse: trademarks data dive in the US and EU

Robert Reading of Clarivate examines years' worth of trademark data in the EU and US, predicting what it might mean for brands

With JPMorgan betting that the metaverse is a $1 trillion yearly opportunity, brand owners are exploring this virtual this space at a rapidly growing rate. The metaverse is a shared immersive virtual world, a seamless convergence of our physical and digital lives in a cyberspace composed of different platforms that is expected to experience exponential growth in the near and medium term.

The metaverse encompasses a variety of events that can be accessed through a virtual reality (VR) headset, via a mobile phone, or in a browser. This creates a whole new (cyber)world of opportunities for brand owners.

We can't talk about the metaverse without mentioning the other area of huge potential for businesses: non-fungible tokens (NFTs). NFTs are essential in the metaverse economy as they enable the authentication of possessions, property, and identity. Given that NFTs are secured by cryptographic keys that can't be deleted, copied, or destroyed, it allows for decentralised verification, which is necessary for the metaverse society to succeed.

While the metaverse and NFTs are two different technologies, trademark data shows that, so far, they have been closely connected. In 2022, there has been a surge in trademark filing activity in relation to both NFTs and virtual worlds.

Putting aside the technical aspects of NFTs and the metaverse (trademark attorneys can breathe a sigh of relief and continue to read on), there have been nearly 10,000 applications filed at the USPTO since January 2021. Of these, 50% cover NFTs only (based on the specification of goods and services), 30% cover both NFTs and the metaverse, and 20% cover the metaverse (but not NFTs).

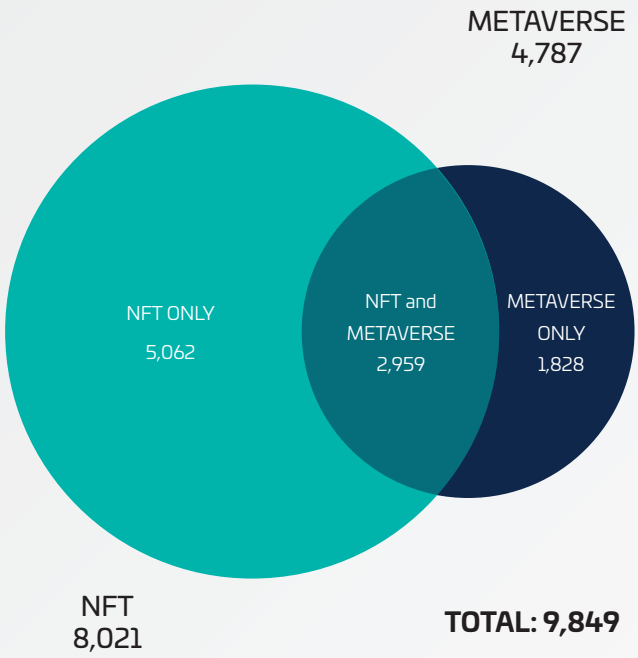
Trademark applications using "virtual worlds" date back many years. Digitalsphere Corporation filed a US application for 'Nerves' covering "object animations in virtual world environments" in class nine as far back as 1996 (US trademark number 75145954). The first NFT-related application was filed in 2018 by Ozone Networks – 'Opensea' (US trademark number 88079626) for an online retail store for the sale of "blockchain-based non-fungible tokens" (class 42).

The trickle of NFT and metaverse applications at the USPTO became a steady flow in 2021, and a flood in 2022.

However, as impressive as the 2022 filing volume appears, the annual numbers disguise a very different recent trend. Since March 2022, filing activity at the USPTO for both NFT and metaverse-related marks has been steadily falling.

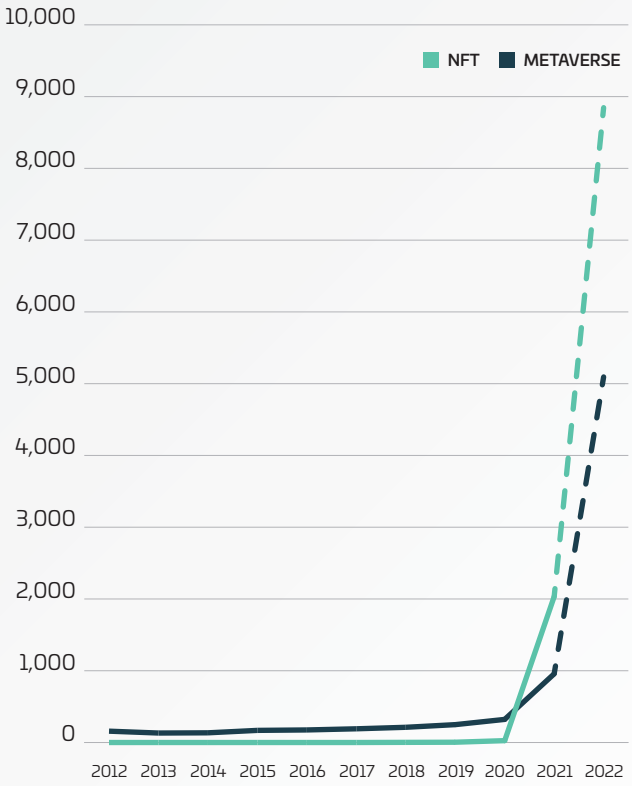
The EUIPO has seen a similar decline in NFT and metaverse applications in recent months.

Figure 1: NFT and metaverse related trademark applications at the USPTO since January 1 2021



Source: SAEGIS trademark database from Clarivate

Figure 2: Annual NFT and metaverse related trademark applications at the USPTO since 2012



Source: SAEGIS trademark database from Clarivate

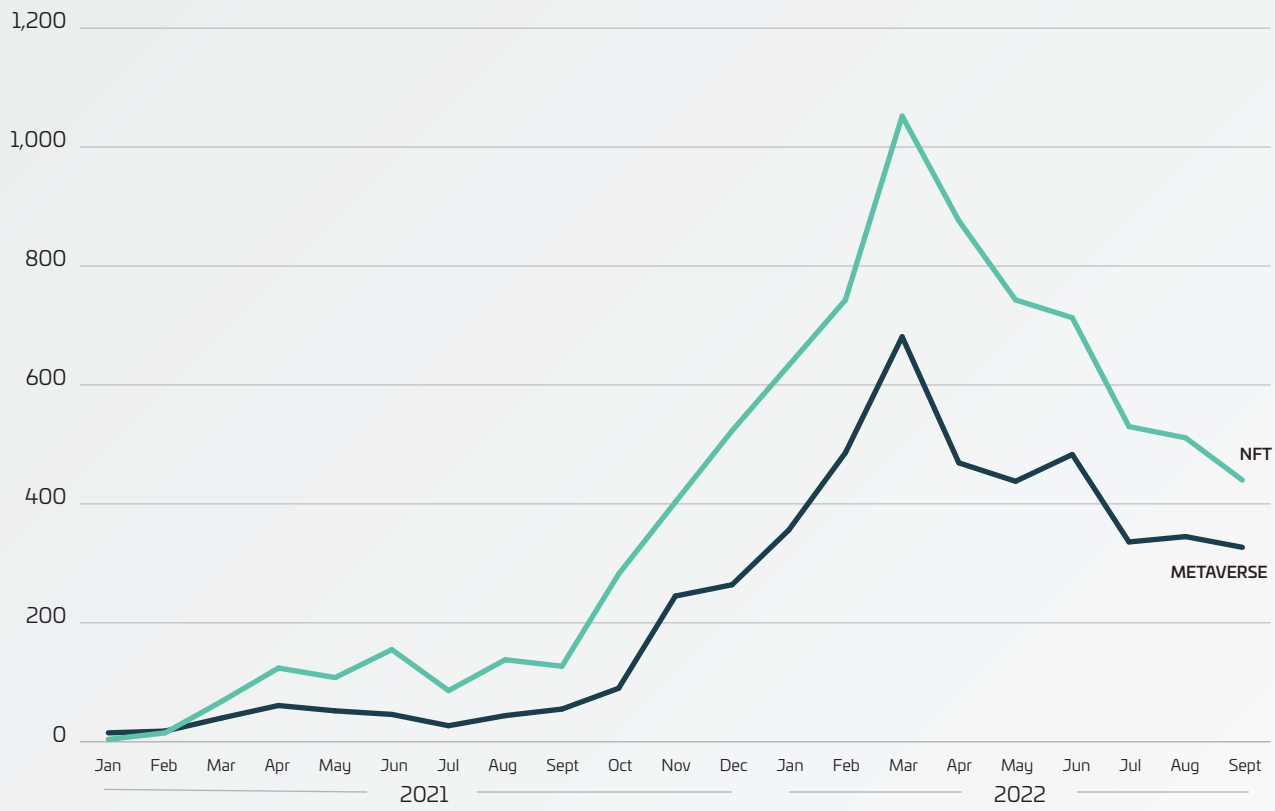
There are several possible explanations for this recent decline. Many new technologies typically have an adoption curve with an early peak ('early adopters') followed by a quiet period, while the more risk-averse larger market decides if it wants to join in. Many of the earlier NFT or metaverse applications may have been filed speculatively as prices of NFTs skyrocketed in 2021. But as prices have tumbled – the NFT of Twitter founder Jack Dorsey's first tweet sold for $2.9 million in March 2021 but failed to attract bids of over $10,000 in April 2022 – appetite for investment in the sector may have waned.

Only time will tell if a second wave of interest comes along, but it's interesting to note that a similar peak was reached in 2018 by applications covering blockchain and cryptocurrencies. It wasn't until 2021 that filing volume at the USPTO for trademarks relating to these two technologies reached the level seen three years earlier. Just like NFT and metaverse applications, blockchain and cryptocurrency filing activity appears to move in tandem. And while 2022 has seen a surge in interest in all four technology areas, NFTs and metaverse applications now outnumber blockchain and cryptocurrency applications.

"In 2022, there has been a surge in trademark filing activity in relation to both NFTs and virtual worlds."

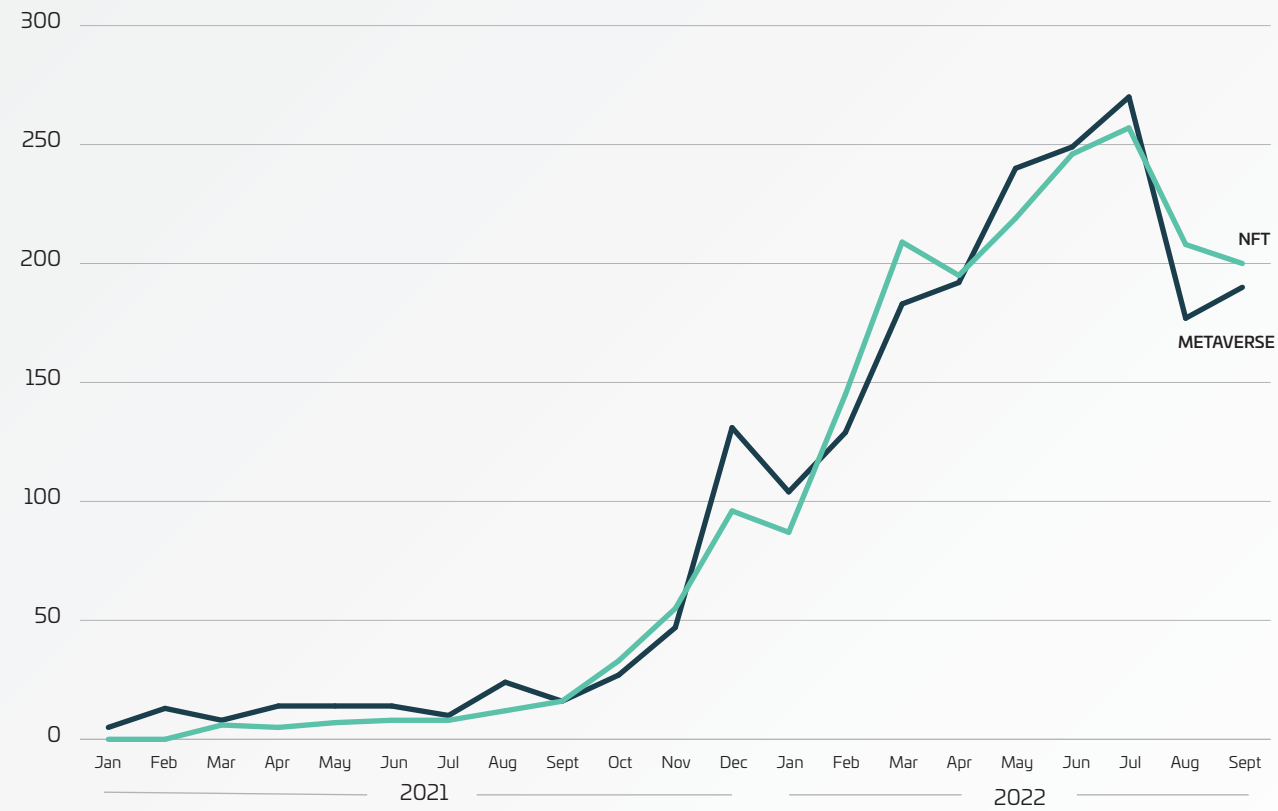
Another interesting insight from the USPTO data can be found in the filing basis field – a US trademark application can be filed on the basis that it is already in use commercially (in which case evidence of use needs to be submitted to support the application), or on the basis that there is an intention to use the mark commercially in the near future. Applications can also be based on an existing foreign trademark application or registration, but the vast majority of US applications relating to NFT and metaverse marks have been filed by US-based applicants, so foreign basis is not relevant. For an application to be accepted for registration, it needs to be in actual commercial use, so typically only around 40% of applications at the USPTO are based on "intent to use".

Figure 3: Monthly NFT and metaverse related trademark applications at the USPTO since January 2021



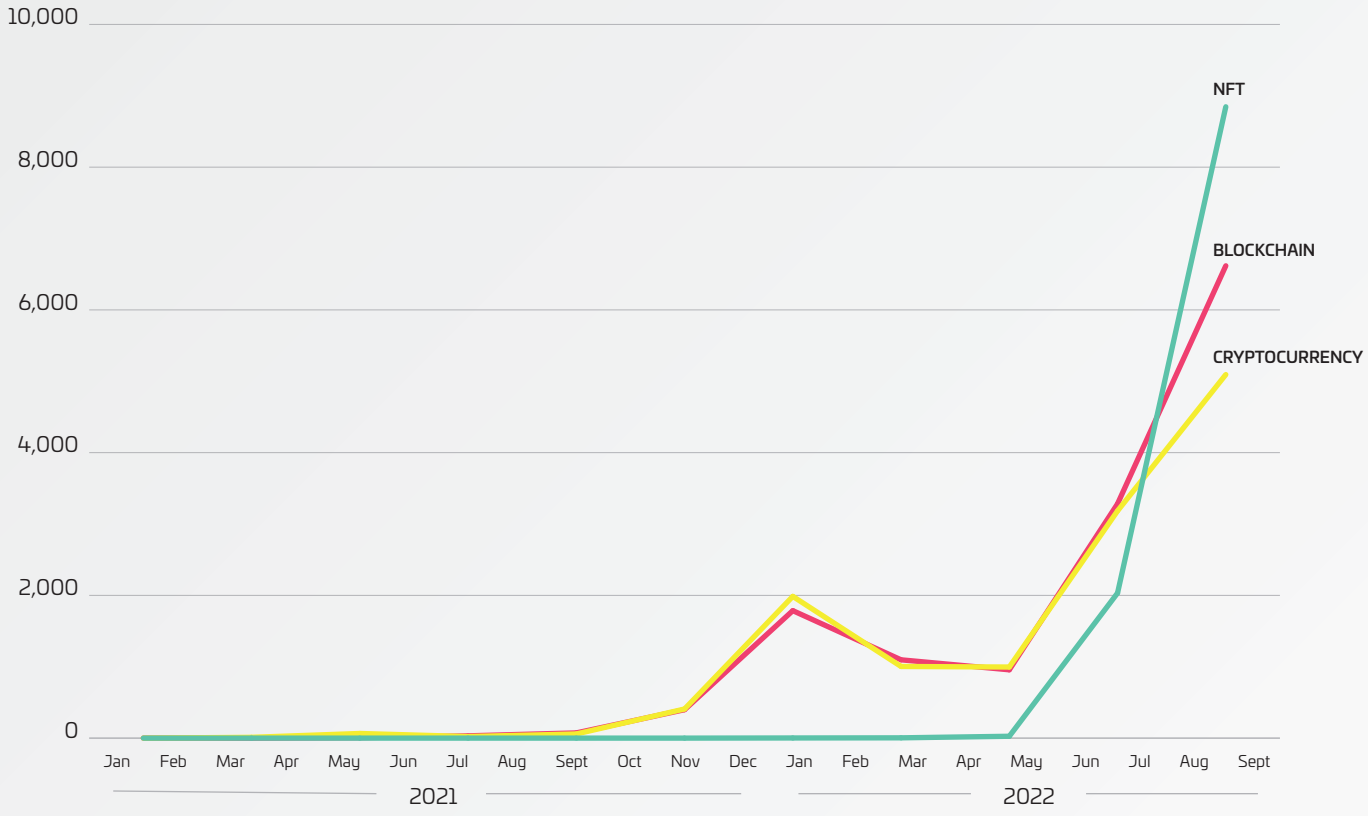
Source: SAEGIS trademark database from Clarivate

Figure 4: Monthly NFT and metaverse related trademark applications at the EUIPO since January 2021



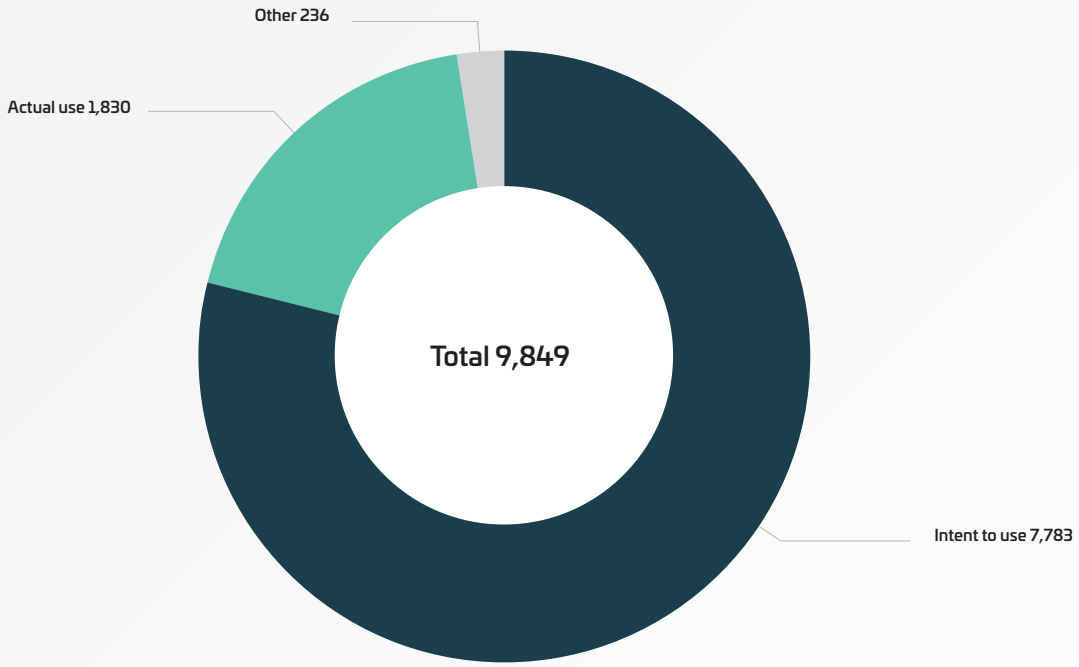
Source: SAEGIS trademark database from Clarivate

Figure 5: Annual NFT, cryptocurrency and blockchain related trademark applications at the USPTO since 2012



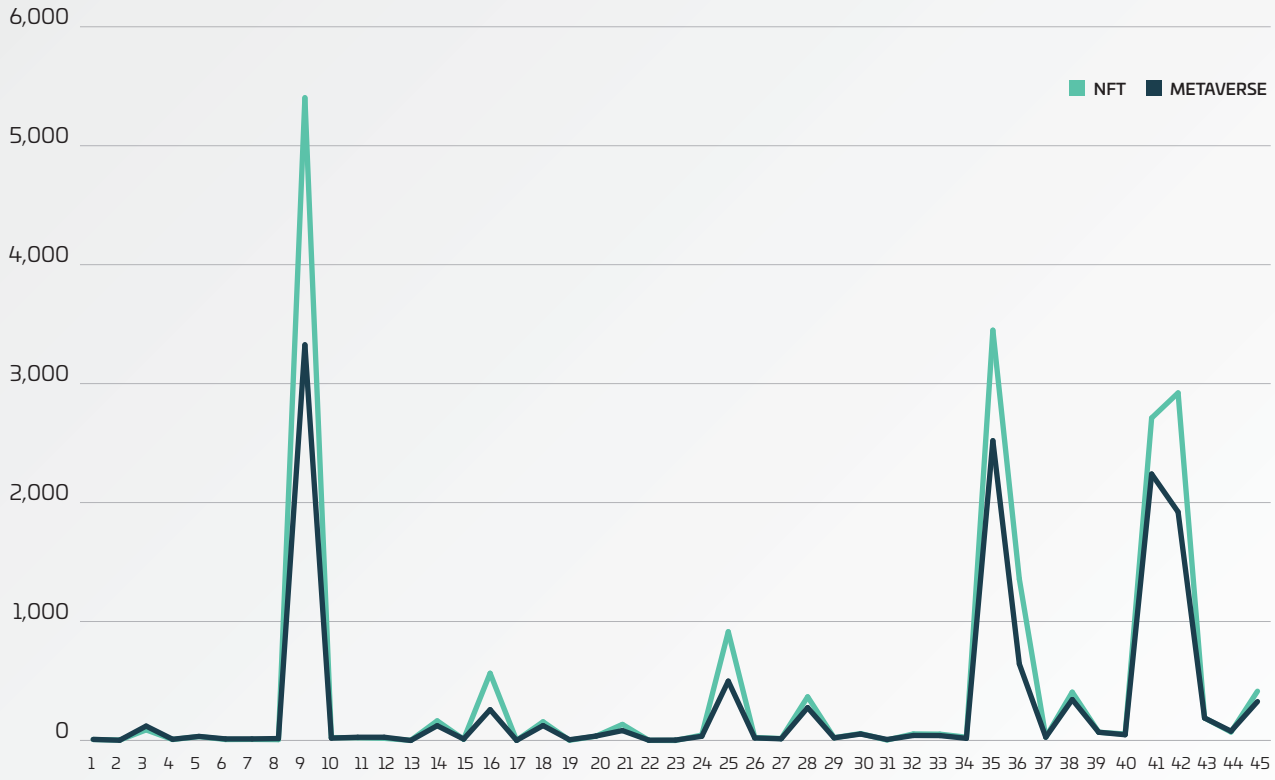
Source: SAEGIS trademark database from Clarivate

Figure 6: Filing basis for NFT and metaverse applications filed at the USPTO in 2021 and 2022



Source: SAEGIS trademark database from Clarivate

Figure 7: Nice class use in metaverse and NFT applications filed at the USPTO in 2021 and 2022



Source: SAEGIS trademark database from Clarivate

However, NFT and metaverse applications are dominated by the "intent to use" filing basis – nearly 80% – which is twice as high as the register average.

This suggests that most trademark applications in the NFT and metaverse spaces do not yet have an actual product available for sale, which is probably not surprising given that the metaverse is still under construction and there is no consensus on the precise nature of these new virtual worlds. The low actual use proportion may also reflect a challenge in providing suitable evidence that shows the use of an NFT or metaverse in actual commerce.

Classification (using the Nice system of 34 goods plus 11 services classes) for NFT and metaverse applications has so far concentrated on four classes:

- Class nine (digital or virtual representations of real-world products; NFTs)
- Class 35 (retail and business services)
- Class 41 (events, training, entertainment)
- Class 42 (technical services – software)

This has an interesting implication for class nine in particular. Already one of the most widely used Nice classes, class nine could be inundated with applications if the owner of every existing trademark for a real-world product decided to file an application for a corresponding virtual brand for use in the metaverse. The current Nice classification divides every real-world product between 34 different (but unequal in size) classes. Physical shoes are in class 25, physical motor vehicles in class 12, and physical food and drink is spread across class 29 to 33. But their virtual counterparts all belong in class nine – and register cluttering could become a very serious problem unless the use of this class is reconsidered in relation to the metaverse.

NFTs and the metaverse will continue to gain interest and, as the metaverse continues to expand, so will business opportunities in this virtual world. According to a Gartner report, 25% of people will spend at least one hour per day in the metaverse by 2026 and 30% of organisations in the world will have products and services ready for the metaverse. This means brands and businesses should prepare for the opportunities this will bring and protect their identity in this new market that is the metaverse.

Robert Reading

Robert Reading is head of content strategy professional services at Clarivate and is based in the UK.

G2/21: mapping plausibility in the EPC

In the second of a two-part series, European patent attorneys at Syngenta and HGF explore contrasting approaches to plausibility in Europe ahead of the G2/21 decision

It is noteworthy that the first prominent decisions expressly asking for plausibility of a technical effect and hence of a claimed technical teaching in the application as filed were issued in relation to biotechnological subject-matter – following directive *98/44/EC* of July 1998 (the Biotech Directive), which has harmonised the law governing biotechnological inventions in the EU. This harmonisation is reflected in the EPC regulations.

The recitals of the directive make it clear that the granting of a patent concerning a biotechnological invention (sequence) "… should be subject to the same criteria of patentability as in all other areas of technology: novelty, inventive step, and industrial application".

This passage reflects the view that the criteria governing patentability should be universal. Industrial application has an important role: "whereas the industrial application of a sequence or partial sequence must be disclosed in the patent application as filed".

The latter is reflected in Rule 29 of the EPC, which stipulates essentially the same. But industrial applicability is something required by all inventions. Furthermore: "a mere DNA sequence without indication of a function does not contain any technical information and is therefore not a patentable invention."

And recital 24 clarifies that "in order to comply with the industrial application criterion it is necessary in cases where a sequence or partial sequence of a gene is used to produce a protein or part of a protein, to specify which protein or part of a protein is produced or what function it performs".

In the first decisions applying what is now termed ab initio plausibility (*T 609/02* of October 2004 and *T 1329/04* of June 2005), the respective claims were indeed concerned with biotechnological inventions.

In *T 609/02*, the claim in question was a second medical use type claim involving the use of a steroid hormone. The second medical use was part of the claim, and hence the alleged technical effect (that the steroid hormone can be used in the treatment of …) was subject to scrutiny under Article 83 of the EPC (sufficiency of disclosure). It was investigated whether what was claimed was sufficiently disclosed in the application as filed. The description as filed provided only vague indications of a possible medical use, which was yet to be identified. The vagueness of the description was considered to represent a fundamental insufficiency that could not be remedied by more detailed evidence filed at a later stage.

In *T 1329/04*, the claim was directed to a sequence encoding a certain polynucleotide (and a specific protein named GDF-9). In view of the prior art, the problem was defined as isolating a further member of the TGF-Beta protein superfamily (transforming growth factor-beta protein superfamily). By recognizing the claimed polynucleotide as a member of this protein superfamily the applicant/proprietor allegedly attributed a function

to that polynucleotide. The question investigated by the board then was "whether or not the problem … was plausibly solved".

While GDF-9 was described in the application as filed, the information provided therein was "insufficient in relation to any function the molecule might have". Functions attributed to the TGF-Beta superfamily were "tentatively and presumptively" attributed to GDF-9 in the description while stressing structural differences between GDF-9 and known members of the GDF-9 superfamily.

The proprietor went so far as to argue that speculations of this kind should be permitted because of the "first to file approach". Yet, in the board's judgment: "enumerating any and all putative functions of a given compound is not the same as providing technical evidence as regard a specific one."

Decisions *T 609/02* and *T 1329/04* are thus in line with the Biotech Directive, as in those cases mere speculations or vague indications were claimed which is contrary to recital (24) of the directive. Mere speculation about potential functions does not correspond to the indication of a function, and a sequence (or hormone) devoid of such an indication, is not a patentable invention. The use of a hormone or the sequence as claimed in the above decisions was respectively lacking an industrial application in the sense of recital (22) of the directive.

Some boards also applied the ab initio implausibility approach, including in biotechnology cases.

It is difficult to imagine a case wherein a purported effect, which was not disclosed in the application, could be taken into consideration in the assessment of patentability without acting against the directive, and thus we are not aware of a no plausibility case concerned with a biotechnological effect.

But the directive also stresses that biotechnological inventions are subject to the same criteria of patentability as other inventions. And indeed, in accordance with Art 27 (1) TRIPS, patents are available without discrimination as to the field of technology. Plausibility considerations are thus not confined to the realm of biotechnological inventions. They reflect the principle that the claims need to be commensurate with the technical contribution to the art. A contradiction between the problem-solution approach and the application of plausibility criteria appears hardly convincing in view of this background.

As outlined previously, plausibility needs to be considered having regard both to sufficiency (Art. 83 EPC) and inventive step (Art. 56 EPC). Confusion may arise when a claim is directed to an (accessible) compound (or sequence) without the technical effect being mentioned in the claim. For what is claimed then is normally not an invention, unless it becomes so by virtue of a technical contribution associated therewith (e.g. the purported technical effect and its use). It is this that must be plausible having regard to the application as filed in accordance with the ab initio plausibility approach. Without it, there can be no invention, no inventive step, and no sufficiency of disclosure of an invention.

National case law relating to plausibility – EPC member states

The plausibility of inventions, or lack thereof, has also emerged from national case law in many of the EPC member states. It should be noted that none of the respective patent laws refer to plausibility, but an increasing number of legal texts relating to the grant procedure include various assessments.

Different courts have applied plausibility in relation to several areas of patent law including sufficiency, obviousness, selection inventions, priority, and industrial applicability.

At the national level, the plausibility threshold is typically applied in invalidation proceedings by the competent national courts, and the assessments vary between European countries.

For example, due to established case law of the German Federal Supreme Court, it is likely that a German court would have readily considered available post-filed data in support of an inventive step, whereas a French court may review this under sufficiency of disclosure.

Below is a summary of some prominent decisions:

Germany

In Germany, whether or not a claimed invention can indeed be realised has been considered a question to be distinguished from the question whether a claimed invention is indeed sufficiently disclosed in the application as filed, namely disclosed such that the skilled person does not consider it as a speculation – the Federal Patents Court (BPatG) held in *3 Ni 37/07 – Cetirizin* (2008): "Whether or not the use of a known compound for the treatment of a specific illness is speculative, is an issue that can arise when the effect is not substantiated by experimental data in the application as filed. This may lead to lack of sufficiency." Mere speculation would hence be considered as insufficiently disclosed in the application as filed.

While mere speculations are to be considered problematic, the claimed scope may generalise beyond described examples without contravening the sufficiency requirement, namely as long as it does not exceed the most generalised teaching as it appears to a skilled person. Under such circumstances, a valid use claim may also encompass the use of hitherto unknown com-

"The Biotech Directive makes it clear that the criteria governing patentability should be universal."

pounds, such as in the Federal Court's (BGH) decision in *X ZB 8/12 – Dipeptidyl-Peptidase-Inhibitoren* (2013).

In the case of open or broad ranges, protection conferred may be limited by the contribution to the prior art, see BGH in *Xa ZR 100/05 – Thermoplastische Zusammensetzung* (2010).

France

While plausibility has not been referred to specifically thus far, the Tribunal de Grande Instance decision in *Mylan v Astrazeneca, 15/05880* in July 2016 held that post-published evidence, relating to an unexpected improvement of bioavailability of an active ingredient, could not be taken into consideration in the assessment of inventive step.

With respect to second medical indications, the Cour de Cassation ruled in December 2017 in *15/19726* that the application as filed must directly and unambiguously disclose the therapeutic application (technical effect). The court held that the skilled person must understand, on the basis of a generally accepted model, that the technical effect is indeed achieved.

Hence some minimal experimental evidence appears required for a therapeutic effect to get established.

UK

Several UK cases have addressed plausibility, mostly as an element of sufficiency of disclosure.

In relation to inventive step, the Court of Appeal in *Generics v Yeda & Teva* (2013), noted: "A technical effect which is not rendered plausible by the patent specification may not be taken into account in assessing inventive step." This corresponds to the approach taken in *T 1329/04*.

Further, the Court of Appeal held in *Regeneron v Genentech* (2013), which refers to *T 609/02*, that "the assertion that the invention will work across the scope of the claim must be plausible or credible".

The Court of Appeal, in *Idenix v Gilead* (2016), also stated that if the assertion was not plausible, then the scope of the patent monopoly would exceed the patentee's technical contribution to the art, rendering the claim insufficient. The Court of Appeal's approach to the assessment of plausibility and the requirement seems to be the same whether raised in the context of sufficiency or inventive step.

The Supreme Court considered plausibility in the context of industrial applicability in *Human Genome v Eli Lilly* (2011). In doing so, the court held that, as a general principle, mere speculation will not do. According to the court, a "plausible" or "reasonably credible" claimed use or an "educated guess" can suffice, wherein such plausibility can be assisted by being confirmed by "later evidence", although later evidence on its own is not sufficient.

The Supreme Court's current position on plausibility (in the context of sufficiency) may be taken from Lord Sumption's judgment (see around paragraph 37) in *Warner-Lambert v Generics* (2018) and summarised as follows:

"First, that a proposition that a product is efficacious for the treatment of a given condition must be plausible.

Second, it is not made plausible by a bare assertion to that effect, and the disclosure of a mere possibility that it will work is no better than a bare assertion.

Third, the claimed therapeutic effect may well be rendered plausible by a specification showing that it was worth trying for a reason, e.g., reasonable scientific grounds for expecting it might work well.

Fourth, although disclosure need not definitively prove the assertion that the product works for the designated purpose, there must be something that would cause the skilled person to think that there was a reasonable prospect that it would prove to be true.

Fifth, such reasonable prospect must be based on a direct effect on a metabolic mechanism specifically involved in the disease, whether known from the prior art or shown in the patent.

Sixth, the direct effect on a metabolic mechanism need not be by way of experimental data, it could be demonstrated by a priori reasoning.

Seventh, sufficiency is a characteristic of the disclosure, and these matters must appear from the patent. This disclosure may be supplemented or explained by the common general knowledge of the skilled person."

In *Human Genome v Eli Lilly*, the plausibility for a pharmacological effect of a claimed compound rested on the fact that it was a member of a known super family and could be expected to exhibit similar functions.

In *Mylan v Yeda* (2013), the England and Wales High Court stated that a technical effect not rendered plausible by the patent specification may not be considered in assessing inventive step, but that later evidence may be adduced to support a technical effect made plausible by the specification (quod non).

In *Regeneron v Bayer* (2013), the High Court said it must be possible to reasonably predict the invention will work with "substantially everything falling within the scope of the claim". Put another way, the assertion that the invention will work across the scope of the claim must be plausible or credible. The products and methods within the claim are then tied together by a unifying characteristic or a common principle. If it is possible to make such a prediction, then it cannot be said the claim is insufficient simply because the patentee has not demonstrated the invention works in every case.

In *Eli Lilly v Janssen* (2013), the High Court defined a two-stage threshold test that assesses post-published data to i.) determine whether the disclosure of the patent made it plausible to the skilled reader that the invention could work across the scope of the claim and ii.) if so, consider whether the later evidence established that in fact the invention could not be performed across the scope of the claim without undue burden.

In *Actavis v Eli Lilly* (2015) the High Court viewed plausibility as a threshold test satisfied by a credible disclosure. In the context of this decision, reference was made to the importance of the claim type and the breadth of the claims to the assessment of plausibility, considering that a single compound with single use was easier to render plausible than wide claims to myriads of compounds, with wide use: "Plausibility is to exclude speculative patents, based on mere assertion, where there is no real reason to suppose that the assertion is true."

In *Warner-Lambert v Generics* (2016) the High Court held that: "a test designed to prevent speculative claiming need go no further than requiring the patentee to show that the claim is not speculative." The specification does not need to provide the reader with any greater degree of confidence in the patentee's prediction. This decision directs courts to assess that plausibility must be apparent from the disclosure of the patent itself.

The Netherlands

The Dutch courts have taken the position that the application must at least make it plausible that the technical problem is solved. In this respect, the Dutch courts appear to adhere closely to the ab initio plausibility approach, whereby post-published evidence may be considered to support a credible disclosure.

Case law consistently states that only technical effects that have been made plausible at the effective date can be taken into account in the assessment of inventive step.

In *Angiotech v Sahajanand* (2009), the Court of Appeal considered that post-published evidence may be considered to supplement and support a credible disclosure.

Furthermore, in *Lilly v Ratiopharm* (2011) and *Glaxo v Pharmachemie* (2012), the Court of Appeal clarified that in vitro tests may be sufficient as proof, and that inclusion of clinical trials at filing is not a prerequisite for patentability, respectively.

Belgium

In Belgium, there has been only a limited number of decisions relating to plausibility in the context of inventive step or sufficiency of disclosure. *GSK v Sanofi* (2007), the Brussels Court of First Instance revoked the Belgian part of a European patent as to protect mere ideas or concepts.

The court reasoned that: "supposing the invention would be novel and the result of an inventive step, it should also be sufficiently mature to be susceptible of an application and therefore described in a manner sufficiently clear and complete for a person skilled in the art to execute it…"

The Antwerp Court of Commerce, in *AstraZeneca v Sandoz* (2013), revoked a European patent when the proprietor relied on post-published evidence to establish improved tolerability for acknowledgement of inventive step, while this problem was not discussed in the specification.

The above selection shows that whether an invention or technical effect has been made plausible in the patent application as filed is a question that courts in several countries have had to deal with. National courts struggle with suitable tests for the plausibility of inventions if it is not supported in the application as filed.

It can be assumed that the pending decision in *G2/21* will serve to harmonise the application of plausibility rules in the EPC countries.

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The view and opinions expressed in this article are those of the authors, and do not necessarily represent official policy or position of Syngenta or HGF, respectively.

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Can NFTs be a legal property?

NFTs are a digital reflection of a real-world asset but the water is muddied as to whether ownership extends to them, says Emma Kennaugh-Gallacher, a senior professional support lawyer at Mewburn Ellis

The world of cryptoassets is a fast-moving and complex one.

Cryptocurrencies such as Bitcoin have been recognised and confirmed by law as a species of property, including in the England and Wales High Court's judgments in *AA v Persons Unknown* (2019) and *Director of Public Prosecutions v Briedis & Anor* (2021).

But the addition of non-fungible tokens (NFTs) to the digital landscape, has added further layers of complexity.

The difficulty with NFTs stems from their similarities with and connections to real-world property. NFTs are a digital reflection of real-world assets but they are so new that the world of law is still working out how existing laws should apply to NFTs and the digital transactions and interactions surrounding them.

The celebrity (or notoriety) gained by NFTs in the last couple of years inevitably means they have been the subject of a few cases before the courts. The most significant of these, *Lavinia Deborah Osbourne v (1) Persons Unknown (2) Ozone Networks trading as Opensea* (Osbourne), considered the crucial question of whether an NFT can amount to legal property. We will consider this case in detail, but first some high-level background on NFTs.

An NFT is a unique (non-fungible), indivisible token that has been minted (created) on a blockchain. They are essentially a digital construct or vehicle for the reference object – the actual asset the NFT represents. These assets are generally artworks or digital music or video files.

In contrast, cryptocurrencies like Bitcoin are both fungible and divisible. This means they can be exchanged for one another like physical currency (one 20p piece is the equivalent of another 20p piece) and can be broken down into units as long as the value remains the same (like two 10p pieces or four 5p pieces).

The key components which make up an NFT are:

A smart contract – this sets out the details of the NFT including:
- The digital artwork, video, photograph, or music file that the NFT represents.
- An actual digital object or a hyperlink to the object.
- Transaction – if condition A (payment) is met, then consequence B (transfer) occurs.

TokenID and contract address – these are both identifiers relating to the NFT. The TokenID is a unique alphanumeric sequence that refers to the specific NFT whereas the contract address refers to where the contract is deployed on the blockchain (such as Ethereum). The contract includes information such as the NFT's transfer history and the number of NFT owners in the collection.

Owner or wallet address – this is the address of the owner of the NFT. A software-generated purse that you use to store NFTs.

How do you make an NFT?

Anyone can create (mint) an NFT from a digital object such as an artwork, a video, a music file, or a photograph. All you need to do is connect your digital wallet to an NFT marketplace and upload the digital file from which you want to mint your NFT.

The basic procedure is very simple but the questions about ownership and entitlement are more complex. While you might own the NFT you have minted, this doesn't mean you own the intellectual property (IP) in the underlying object.

Can an NFT be a legal property /asset?

Disputes over ownership and entitlement to IP have long been the subject of litigation so, when it comes to the IP in NFT reference objects, it seems likely that these well-established principles will apply.

However, the courts now face an entirely new question: can NFTs amount to items of legal property in their own right? The courts had not given a strong indication of their position until Judge Mark Pelling KC considered this very question in his landmark High Court decision earlier this year in *Osbourne*.

The claimant, Lavinia Osbourne, is a fintech and blockchain specialist and the founder of the popular and successful "Women in Blockchain Talks" podcast.

Osbourne owns two NFTs which represented digital artworks from the Boss Beauties series (the value attributed to them by the court was £4,000 ($4,616) but it was understood that they were of "particular, personal and unique value to the claimant").

The NFTs were removed without permission from her MetaMask digital wallet. They later reappeared, attributed to wallets belonging to unknown individuals.

In filing these proceedings with the court, Osbourne sought (and was granted) applications for:
- An interim injunction to freeze the stolen NFTs (preventing any further transfers).
- An order under the Bankers Trust jurisdiction which would require OpenSea to provide information enable the identification and tracing of the wallets and their owners.

Decisions to grant freezing and proprietary injunctions regarding stolen cryptocurrency have been issued before, such as in *Ion Science v Persons Unknown* (unreported), but *Osbourne* is the first instance of a court issuing a freezing injunction in respect of NFTs as a distinct class of cryptoasset.

Pelling KC found: "There is clearly going to be an issue at some stage as to whether non-fungible tokens constitute property for the purposes of the law of England and Wales, but I am satisfied on the basis of the submissions made on behalf of the claimant that there is at least a realistically arguable case that such tokens are to be treated as property as a matter of English law."

In recognition of the scarcity of legal precedent in this area, the Law Commission of England and Wales published a consultation paper in July 2022. The paper sets out various law reform proposals regarding the recognition and protection of digital assets and sought public comments up until November 4, 2022.

We await the outcome of the consultation with great interest and expectation.

Emma Kennaugh-Gallacher

Emma Kennaugh-Gallacher is a senior professional support lawyer at Mewburn Ellis in Bristol.

CITMA: why our trademark and IP system needs urgent support

UK attorneys are being let down by a system that is being taken advantage of by scrupulous overseas players, explains Rachel Wilkinson-Duffy, president of CITMA

As the government looks to supercharge growth and support businesses post-Brexit, it must strengthen our trademark and intellectual property system to support innovators who can help deliver on those goals.

The government's flagship Brexit legislation, currently making its way through Parliament, provides the platform to do so.

Already, industries that rely on our trademark and IP system contribute £770 billion ($868bn) per year to GDP. These are our small-scale start-ups, our SMEs and household names like Astra Zeneca and Dyson. These are innovators that think outside the box and take their product – and the UK's reputation – to the world stage.

But they are being let down at present by a system that is being taken advantage of by scrupulous overseas players.

Following Brexit, UK trademark and IP representatives lost the right to appear before the EUIPO – and they can't appear before the USPTO, either. That's two of our largest markets, blocking our representatives from appearing there.

Here, however, our loose rules mean that foreign practitioners can use our system with little-to-no connection to the UK.

New IP minister urged to tackle UKIPO representation

George Freeman has been reappointed UK minister with responsibility for intellectual property, it was confirmed on November 21.

Freeman held the role in former Prime Minister Boris Johnson's government from September 2021 until the latter's resignation in July this year.

He was replaced by Dean Russell during Liz Truss's short-lived tenure as prime minister, but the role became vacant in October after Truss resigned.

Rachel Wilkinson-Duffy, president of the Chartered Institute of Trade Mark Attorneys (CITMA), welcomed Freeman's reappointment but expressed concern over the delay.

"His background and special interest in the sector is a great asset, but the delay in seeing his appointment means there is no time to waste in tackling its critical issues," she said.

Wilkinson-Duffy urged Freeman to adopt CITMA's proposals for tighter rules on foreign attorneys' rights of representation at the UKIPO.

"By ensuring that representatives are appropriately regulated and qualified, we will help to deliver an excellent IP environment that works in the interests of our innovators rather than foreign practitioners," she said.

The vacant IP minister brief had been a source of frustration for professional bodies in recent weeks and attracted criticism from the opposition Labour Party.

As recently as November 9, the government told shadow business minister Chi Onwurah that it could not confirm when the post would be filled.

Onwurah told Managing IP at the time that the delay indicated a lack of seriousness from the government on IP.

There have been 13 IP minister appointments in the past 12 years, including second terms for Freeman and Jo Johnson (brother of Boris), who held the post from 2015 to 2018 and again for three months in 2019.

Not only is that unfair for our experts who are locked-out from overseas systems and are competing on an uneven playing field, but it means that our system – our public service – is opened up to use by foreign actors.

New research conducted by CITMA reveals the extent of the problem: foreign attorneys or firms now account for 35% of firms in the top 100 trademark filers at the UKIPO.

That is up from 16% in 2019 before our departure from the EU.

One overseas-based company (Haiwai Consulting) managed to file 1,532 trademark applications on behalf of its clients in just a six-month period last year, having never filed a single application previously.

This shows our system is being run down.

Thousands of applications are made every year by foreign practitioners looking to take advantage of our public infrastructure – even though their clients sometimes have no intent of setting up business, employing people and sharing wealth here.

This all adds cost and complexity to proceedings and allows unregulated overseas practitioners to give poor advice because they don't understand our system.

Worse still, because they are overseas-based, these practitioners aren't regulated and so there is no protection for consumers when things inevitably go wrong.

"Thousands of applications are made every year by foreign practitioners looking to take advantage of our public infrastructure."

Jacob Rees-Mogg's Retained EU Law (Revocation and Reform) Bill, better known as the 'Brexit Freedoms Bill', presents the opportunity for a simple fix.

It must be strengthened so that representation requirements are tighter to prevent unregulated and unqualified representatives taking advantage of our lenient system.

This is a cost-free fix that will deliver a true Brexit dividend and will free our innovators up to do what they do best – take their product to the world and deliver the growth we all want and need.

Rachel Wilkinson-Duffy

Rachel Wilkinson-Duffy is president of CITMA.

EUIPO: a look back at 2022

Christian Archambeau, executive director of the EUIPO, looks back at 2022 and addresses the expected drop in EUTM filings

When we drew up our plans for 2022, we expected our traditionally high numbers of EU trademark applications continue to grow, with a return to normality after the pandemic and a subsequent economic recovery.

Instead, we have witnessed armed conflict return to our doorstep, and unprecedented economic turmoil across the whole of Europe, including the highest level of inflation in the Eurozone since records began in 1997.

For only the fourth time in the history of EUTM filings, the end of 2022 is set to see a decline in the number of applications when compared to the previous year.

However, even though direct filings for both EUTMs and designs have fallen, international registration filings, those coming from WIPO, have increased when compared to last year. This has somewhat mitigated the effect of the decrease in direct applications.

In fact, in the third quarter of the year direct filings with the EUIPO were down 15% compared to 2021. By the end of October, the total number of EUTM filings received stood at 145,102, with 117,935 direct applications and 27,167 international registration filings. We expect to end 2022 with around 173,500 applications. By the end of the year, this could mean a decrease of approximately 12% compared to 2021.

However, when compared with the last pre-COVID year, the overall figures paint a different picture. If we look back to 2019, this would mean an increase of 7.5% on filings received and a minor decrease of 2% in comparison with 2020.

This trend is expected to continue into 2023, with a slight growth of 1.3% forecast for trademarks and designs when compared to 2022.

Looking closer at international registrations, these continue to grow, with an increase of around 11% by the end of September 2022 compared to the same period in 2021. The US accounts for 30% of the weight of these filings and is driving the positive numbers.

On the other hand, design filings show a more stable trend when compared to 2021 data. In the same way as EUTMs, the number of design filings are sustained by a growth of 14% in international registration filings, while direct filings have slightly decreased compared to last year by 6%.

What has caused the decrease?

It is unlikely that there is any single reason behind the downward trend in filings.

In 2021, we witnessed a highly volatile economic context, with an unprecedented volume of applications. This was influenced by a number of factors, such as signs of recovery and the vast adoption of e-commerce

in the wake of the pandemic. Global volatility has persisted for much of 2022, but this time with a reverse effect on filings.

In particular, filings from China, which was the top filing country in terms of EUTM applications in 2020 and 2021, have dropped by 40% during the course of 2022.

This may be due to a number of factors, including the discontinuation of state incentives to apply for intellectual property rights. Nevertheless, China remains the country which filed the second most EUTMs in 2022, only behind Germany, and is the top filer for designs.

In 2022, the global financial uncertainties and the COVID-19 pandemic have been accentuated by the Russian invasion of Ukraine, which in turn has had a negative effect on the global rise in commodity prices and inflationary pressures. We are facing the highest level of inflation in the Eurozone since record-keeping began in 1997 and like the rest of the world, we find ourselves in a delicate spot at the moment.

Measures under way

At the EUIPO we have already taken proactive measures, not only to weather the remainder of 2022, but also to start 2023 on the best possible footing.

Our efforts to modernise the technical infrastructure and to keep up with innovation over the past years have enabled us to react effectively to the current situation. We have introduced new technologies, such as the new e-filing form based on AI, and have also simplified processes, all of which contribute to improving and facilitating the work of the office.

Moreover, to adapt to the drop in applications the office has implemented an amending budget for 2022 with reductions in expenditure. More specifically, we have reassessed and prioritised strategic projects based on their return on investment. We are also curtailing running expenditure and activities and have set significant internal efficiency targets to compensate for the adverse economic conditions.

All in all, our 2023 work programme has been prepared with all these opportunities and challenges in mind.

In fact, to continue helping European businesses and drive filings up we will roll out a new SME Fund that is currently under discussion. The fund covers eligible fees for trademarks and designs at national, regional and EU levels as well as fees for national patents.

Next year the fund will also cover new fees, namely European patent and plant variety fees. The fund is already proving very successful, with over 20,000 applications received so far.

"We are facing the highest level of inflation in the Eurozone since record-keeping began in 1997 and like the rest of the world, we find ourselves in a delicate spot at the moment."

EUIPO history in numbers

Trademark applications have been rising steadily year-on-year since 2008, following the global financial crisis. However, this is not the first time we have experienced a drop in application volumes.

The first decrease took place in 1997, following a large number of filings (43,000 EUTM applications) received in 1996, the first year of the EUIPO's operations. 1997 saw a return to normal with 27,300 trademarks filed.

In 2001 and 2002, after the '.com' crisis, fillings also decreased, predominantly in 2001, when there was a decrease of 15%. In 2008, following the global financial crisis, there was a drop in the number of filings, albeit minor, in comparison to the 2007 levels (1%).

In spite of these drawbacks, the office has shown sustained growth through the years and has proved to be a key contributor to the modernisation of the IP landscape in the EU. In fact, since our inception, we have cut the average time to register a trademark from eight months to five months, we have become a fully-fledged digital organisation and transformed the IP world through our cooperation activities.

Even with the pandemic, the uncertainty, and the economic instability that have characterised these recent years, the office has successfully adapted to a heavy workload while maintaining a high-quality service.

In 2022, the EUIPO absorbed the extraordinarily high volumes of filings that came from 2021 and did so while fulfilling its service charter commitments, in particular with regard to timeliness.

Looking into the future, I am confident that our investment in an agile and innovative ecosystem will allow for timely, flexible, and efficient reactions to any situation.

Christian Archambeau

Christian Archambeau is executive director of the EUIPO. He will leave his role next year.

Analysis of China's Guidelines for Registration Review of AI Medical Devices

Xiaoyan Zhou of Purplevine IP explains how to protect IP in the rapidly developing area of AI medical devices in China, and the risks involved

Accelerating digital and AI transformation has become a significant direction of development. To keep up with this trend, the Chinese government has attached particular significance to medical AI development in recent years. In April 2018, the General Office of the State Council issued the *Opinions on Promoting the Development of "Internet+ Medical Health"*, proposing to promote "Internet+", the application of AI.

The Chinese government has also taken a step forward in registration management. On March 9 2022, the Center for Medical Device Evaluation issued the *Guidelines for Registration Review of AI Medical Devices* (the '*Guidelines*'), which aim to guide applicants to establish the life cycle of AI medical devices and prepare the registration application documents. The *Guidelines* also regulate the requirements of technical reviews of AI medical devices, providing a reference for the systematic review of AI medical devices and quality management software.

I. Definition of AI medical devices

It is paramount to clarify the definition of AI medical devices. According to the *Guidelines*, "AI medical devices" refers to medical devices that apply AI technology to analyse "medical device data" to achieve their intended use; in particular, medical use. The *Guidelines* also define the scope of medical device data and AI technology.

Thus, the three key elements of an AI medical device are:

- Medical device data;
- AI technology; and
- Medical use.

If an AI medical product operates based on non-medical device data, or a medical device achieves non-medical uses by using AI technology, it is not considered an AI medical device.

II. Risks of AI medical devices

There are a few risks involved in AI medical devices. An understanding of the risks and Chinese legislative concerns would help medical device companies to have a full grasp of the *Guidelines*.

1. Overfitting and underfitting with an algorithm

Overfitting means an algorithm is overtrained to the extent that it tries to cover all the training data set and starts to learn irrelevant information within the data set. Underfitting means that an algorithm is not fully trained and thus cannot capture a relationship in the data set accurately. Overfitting and underfitting reduce the generalisation capability of the algorithm.

2. Inaccuracy of the clinical decision support system

The inaccuracy of the clinical decision support system may cause false negatives and false positives. False negatives may lead to delays in follow-up treatment. This can be consequential, especially for patients with rapidly progressive diseases. False positives may lead to overtreatment, which does not benefit the patients.

Algorithms used to manage data processing and testing in AI medical devices may also have risks in undervaluing or overvaluing information.

3. Issues of imported AI medical devices

There are risks to using imported AI medical devices given the different medical standards between China and foreign countries. These differences include race, epidemiological characteristics, and standards on clinical diagnosis and treatment.

It is obvious that the risks of AI medical devices mainly come from the software, such as:

- Algorithms;
- Data; and
- Decision-making mechanisms.

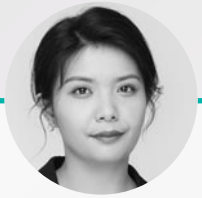
Among them, the algorithm is at the core of AI medical devices; thus, meticulous attention should be given to the risk management of the algorithms.

III. Analysis of the Guidelines

The development of AI technology is driven by algorithms, which are based on a model/data, and computing power. While a model/data is the foundation of AI technology, the algorithm is the core of AI technology, and computing power guarantees the operation of AI technology.

The generalisation capability of algorithms (which refers to whether the algorithms can properly adapt to new data) is the key breakthrough to test the risk level of the algorithm in AI medical devices. Thus, the *Guidelines* require that the generalisation capability algorithm of the products should meet the requirements before and after launch, and during product renewal.

"The generalisation capability of the algorithm of AI medical devices is strictly scrutinised."



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Xiaoyan is a former patent examiner in the Patent Examination Cooperation (Sichuan) Center of the Chinese patent office, the CNIPA.

She has experience in the substantive examination of over 500 invention patents. This has included a large number of Patent Cooperation Treaty applications with applicants such as Ford, Toyota, Volkswagen, BYD, NIO, and Contemporary Amperex Technology.

Xiaoyan is a qualified patent attorney in China.

"AI medical device companies should diversify their patent portfolios."

To manage the risks of AI medical devices, the generalisation capability of the algorithm of AI medical devices is strictly scrutinised. The *Guidelines* put forward the following requirements:

1. Data acquisition

- Adequacy and diversity of data;
- The scientificity and rationality of data distribution; and
- Quality control for data collection, data collation, data annotation, data set construction, etc.

2. Algorithm design

- Clarify the basis of algorithm selection, including the reasons and basic principles of selection;
- Provide the training data volume-evaluation index curve to prove the adequacy and effectiveness of algorithm training. If it cannot be provided, it is necessary to elaborate on the reasons and provide alternative evidence; and
- As an important part of software verification, algorithm performance assessment needs to evaluate the algorithm design results based on the data sets. It should comprehensively consider the assessment requirements – such as the avoidance of false negatives and false positives, repeatability and reproducibility, robustness, real-time performance – to verify that the algorithm's performance meets the objective of the algorithm's design and acts as the basis of software verification and validation.

3. Validation and qualification

- Clinical validation: the evaluation should be based on the core function or the core algorithm, in combination with the intended use and maturity; and
- A comparative analysis of the algorithm's performance should be conducted.

IV. How to protect your IP of AI medical devices

Algorithms are very important for AI medical devices, and the *Guidelines* put forward requirements in data acquisition, algorithm design, validation, qualification, etc. Therefore, as the core advantages of some AI medical device companies, the IP of AI algorithms and the underlying technologies should be rigorously protected:

- Given that algorithms cannot be patented, AI medical device companies are advised to apply a combined approach of trade secret protection and patent applications. To be more specific, the AI algorithm can be protected as technical information as a type of trade secret. This requires a company to set up a thorough technical information management system and relative support. To protect the IP of the algorithm further, AI medical device companies should try to frame the algorithm as a module of the AI medical device (for a method patent) to obtain patent rights.
- On the technical side, companies should avoid including too much immaterial information in the technical features of the claims during the patent drafting process. By avoiding this, companies are facilitated in evidence collection for potential infringement in the future. Furthermore, the focus of the technical solution section should rest on the core technology rather than its application. Therefore, it is recommended to consider how to reflect the innovation of the algorithm or the underlying technology at the application level when drafting patents for AI medical devices.
- AI medical device companies should also diversify their patent portfolios; for example, apply for a method patent for the algorithm, a utility model patent for the mechanical design of the AI medical device, and a design patent for the interface of the AI medical device display. The diversification of the patent portfolio helps to strengthen the protection of an AI medical device and its algorithm.

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Chinese SPC elucidates test for evaluating common knowledge evidence

Xiaohui Wu of Wanhuida Intellectual Property reports on a ruling by the Supreme People's Court of China that emphasises that the determination of common knowledge in the assessment of inventiveness should be incontrovertible

In the assessment of inventiveness in patent prosecuting and invalidity procedures, common knowledge evidence is often cited as a benchmark of the technical knowledge and cognisance of persons skilled in the art. However, common knowledge is ill-defined in China's patent laws and regulations. Only the Guidelines for Patent Examination enumerate three forms of common knowledge evidence:

- Textbooks;
- Technical manuals; and
- Technical dictionaries.

In the absence of a clear definition, stakeholders often struggle in ascertaining common knowledge in practice. The Supreme People's Court (SPC) leverages *Targetpharma Laboratories et al. v. CNIPA* to expound the test for evaluating whether books could be admitted as common knowledge evidence.

The case relates to the invention patent application of "Tumor-targeted TNF [tumour necrosis factor]-related apoptosis-inducing ligand's variant and the application thereof" (the 'application'). The China National Intellectual Property Administration (CNIPA) rejected the application on the ground that the application was devoid of an inventive step. The rejection was affirmed in the re-examination procedure, where the CNIPA cited Volume 8 of the *Frontier of Tumor Research* as evidence of common knowledge to support the finding of obviousness of the application.

The patent applicants – Targetpharma Laboratories and High-tech Research Institute of Nanjing University, Changzhou – filed an administrative lawsuit to the Beijing Intellectual Property Court (the 'Beijing IP Court') challenging the re-examination decision.

The Beijing IP Court sided with the plaintiffs, holding that Volume 8 of the *Frontier of Tumor Research*, which was neither a textbook nor a technical dictionary, is a mere periodical on tumour research. The CNIPA erred in using such as common knowledge without assessing the admissibility of the documented technical knowledge. The Beijing IP Court quashed the CNIPA's decision and ordered the agency to remake a decision in another round of re-examination procedure.

The CNIPA appealed to the SPC, contending that periodicals, as a continued publication, should use an ISSN (International Standard Serial Number) rather than an ISBN (International Standard Book Number). Given that Volume 8 of the *Frontier of Tumor Research* only has an ISBN, it is not a periodical, but a book. Volume 8 of the *Frontier of Tumor Research* documented the knowledge related to NGR sequence polypeptides, which was cited in the re-examination decision, is known common knowledge in the art.

SPC decision

On August 13 2020, the SPC dismissed the appeal and upheld the decision made by the Beijing IP Court.

The SPC reasoned that, in general, whether relevant technical knowledge may be classified as common knowledge could be proved by evidence in the technical art, such as technical dictionaries, technical manuals, and textbooks. Where the aforesaid approach fails, stakeholders may resort to evidence (such as numerous patent literatures, periodicals, and magazines) that is not common knowledge in the art yet is mutually corroborative to prove that the technical knowledge is common knowledge.

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Xiaohui Wu is a senior patent counsel at Wanhuida Intellectual Property. Her areas of technical expertise are biology, pharmaceuticals, chemicals, and chemical engineering.

Xiaohui's experience as the R&D project director at a local pharmaceutical company has equipped her with a better understanding and anticipation of the needs of the firm's biopharma clients in respect of patent prosecution, enforcement and dispute resolution field.

Xiaohui was one of the lead counsels that helped a pharmaceutical multinational corporation enforce its invention patents against the infringers offering to sell products exploiting the client's patents in two cases, which are selected as one of the National Ten Exemplary Patent Administrative Enforcement Cases in 2019 and 2018 by the China National Intellectual Property Administration.

However, this approach is subject to a high bar of standards of proof. In assessing whether literature other than technical dictionaries, technical manuals, and textbooks documents fundamental technical know-how in this art and thus should be admitted as common knowledge evidence, courts need to factor in metrics such as the carrier form, content and characteristics, audience, and dissemination scope.

The SPC analysed the admissibility of Volume 8 of the *Frontier of Tumor Research* as follows: firstly, as the acronym for an International Standard Book Number, ISBN has been used in China for many years. The fact that Volume 8 of the *Frontier of Tumor Research* has an ISBN substantiates that the publication falls under the category of books, if judging from the carrier form.

Secondly, in terms of content and characteristics, the publication is a book, but not a textbook of general nature. The preface of the book states its objective as keeping the peers and researchers abreast of the world's progress in tumour research in layman's terms, which makes it a combination of a treatise, an overview, a commentary, and a popular science reading. It indicates that the book aims to introduce the latest progress in terms

"Stakeholders often struggle in ascertaining common knowledge in practice."

"Common knowledge evidence carries considerable weight in an assessment of inventiveness."

of tumour research around the world, rather than to provide general technical know-how in the field. Thus, the book is not a textbook in the usual sense.

Lastly, judging from its audience and dissemination scope, the publication could hardly be ascertained as a textbook. The "content abstract" on the copyright page of the book indicates that it is not a textbook in the usual sense, but a reference book for professional researchers. The SPC therefore concluded that the cited publication is a book, not a textbook in the usual sense, which definitely does not qualify as common knowledge evidence.

Common knowledge evidence carries considerable weight in an assessment of inventiveness. That is why the SPC underlines in its decision that the determination of common knowledge should be incontrovertible and supported by sufficient evidence or argument and should not be made lightly.

Tests of common knowledge evidence

Common knowledge evidence is used as a benchmark of the fundamental technical know-how and competence of persons skilled in the technical art. The technical means that are being assessed fall under the sphere of common knowledge, provided such means have been universally acknowledged in the art. With regard to carrier form of the evidence, technical dictionaries, technical manuals, and textbooks that are extensively used as reference books may be admitted as common knowledge evidence. Books and other publications need to pass the same test to be admitted as common knowledge evidence.

In other words, if the cited evidence focuses on the latest research progress, it does not suffice to prove that the documented technical know-how has been widely used in the art, unless corroborated by the breadth and depth that such technical know-how has been utilised by persons skilled in the art.

The CNIPA submitted during the appeal several items of prior art literature in an attempt to prove that the technical means at issue fall under the category of common knowledge. The newly adduced evidence was rejected by the SPC on the ground that it altered the grounds and basis of the findings of the litigious decision. Nonetheless, the SPC affirmed that the CNIPA could still introduce the evidence and solicit comments of the applicants when remaking its re-examination decision.

It remains to be seen whether Volume 8 of the *Frontier of Tumor Research*, in combination with other literature, could prove the technical means at issue may be perceived as common knowledge in the CNIPA's second round of re-examination procedure.

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GERMANY

Ferrari Front Kit saga: the protection of parts of a complex product

Bird & Bird

Roman Brtka

This article looks at the German Federal Court of Justice judgment (BGH, judgment of March 10 2022, docket no. I ZR 1/19) following the preliminary ruling by the CJEU in the Ferrari Front Kit case (CJEU, judgment of October 28 2021, docket no. C-123/20).

Facts

The star of the case is Ferrari's top-of-the-range car model 'FXX K', which was presented to the public for the first time in a press release in December 2014. One of the photographs used showed the front view of the car and its typical 'V'-shaped element on the front hood. Ferrari omitted to file for registered community designs (RCD) for the car's design and the 'V'-shaped element.

A tuning kit produced by a Mansory could be used to change the appearance of another less exclusive Ferrari car model in a way that its design came close to that of the 'FXX K'. Particularly, a similarly looking 'V'-shaped element was part of the tuning kit. Ferrari claimed an infringement of an unregistered community design (UCD) in the design of the 'V'-shaped element of its 'FXX-K' car model.

Decision of the CJEU

After losing the first and second instance, Ferrari appealed to the BGH, which referred to the CJEU, inter alia, the question of whether a part of a product could be protected by an UCD if the part had only been published as part of the whole product. German courts responded negatively to this question. However, the CJEU ruled that such protection was possible and that Ferrari might rely on a UCD for the 'V'-shaped element if the appearance of the 'V'-shaped element was 'clearly recognisable' delimited by lines, contours, colours, shape or a special surface structure and thus itself creates an 'overall impression'.

Decision of the BGH

Of course, the BGH followed this approach and referred the case back to the court of second instance for a final decision on the merits, taking into account the ruling of the CJEU.

In addition, the BGH also commented on passing-off claims based on unfair competition law. Such claims might be possible if the manufacturer of the original product can show the individual and distinctive character of a product (so-called *wettbewerbliche Eigenart*). According to the BGH, the individual and distinctive character of a part of a product cannot be assessed independently of the product.

Practical consequences and outlook

It is now clear that a part of a product can be protected by an UCD, even if the part had only been published as part of the product. However, such protection will only be granted if the part is clearly recognisable. The necessary demarcation might be established by appropriate design means in the design creation process. However, insignificant or arbitrarily delimited parts are not likely to enjoy protection.

Neither the CJEU nor the BGH, however, has addressed the question of whether parts of a RCD might also enjoy protection as a UCD individually. In the author's opinion, the answer is yes. It should not really make any difference whether the part for which protection is sought is a part of a real product or of the graphic representation in the design register.

While the legal position of a manufacturer of original products is strengthened, it is nevertheless recommended to also file for parts of a product for an RCD. The scope of protection is greater and the term of protection is considerably longer. While an RCD enjoys absolute protection for up to 25 years, a UCD only enjoys protection against imitations for three years.

GERMANY

Proportionality defence v compulsory licence: the decision of the Düsseldorf court

Maiwald

Marco Stief

In July 2022, the Düsseldorf Regional Court specified the handling of Section 139 (1), sentence 3 of the Patent Act in the field of pharmaceutical litigation, concerning the so-called objection of disproportionality.

The introduction of the objection of disproportionality

The objection of disproportionality was introduced by the Second Act to Simplify and Modernise Patent Law and has been in force since August 2021.

According to the new objection, a claim for injunctive relief is dismissed if the claim would lead to disproportionate hardship for the patent infringer or third parties, without being justified by the exclusive right granted by the patent, due to the circumstances of the case and the requirements of good faith.

What at first sight appears to be a corrective to the German injunctive relief system merely constitutes a clarification of the requirement of good faith (Section 242, German Civil Code) according to the conception of the legislator. In the earlier *Heat Exchanger* decision of the Federal Court of Justice (judgment of May 10 2016 – X ZR 114/13), good faith was already taken into account in the context of a decision on the granting of an expiry period for the use of a patent.

On the one hand, this legislative

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clarification aims to counter the problem that patent law objections to the smallest product components can paralyse entire production chains and thus have serious economic consequences.

On the other hand, as mentioned in the explanatory memorandum to the law, the criterion of third-party interests can be used to alleviate a wide range of critical effects of injunctive relief; inter alia, the supply of vital products and the protection of important infrastructure. The Düsseldorf Regional Court analysed these third-party interests in its judgment of July 7 2022 (Case No. 4c O 18/21).

Facts

The British biotechnology company NuCana accused the US pharmaceutical company Gilead of infringing patent EP 2 955 190 with its hepatitis C drugs Epclusa, Harvoni, Sovaldi, and Vosevi. The active ingredient sofosbuvir, patented by NuCana, is contained in Gilead's hepatitis C drugs.

In the infringement proceedings before the Düsseldorf Regional Court, Gilead invoked the objection of disproportionality with reference to patients' interests. The legal validity of the patent had been previously confirmed upon an unsuccessful notice of opposition filed by Gilead against the patent granted to NuCana.

The judgment of the Düsseldorf Regional Court

In its judgment of July 7 2022, the Düsseldorf Regional Court first found an infringement of patent EP 2 955 190 and then dealt with Gilead's alternative objection of disproportionality.

The court had previously refused to stay the proceedings until the conclusion of the opposition appeal proceedings, referring to the negative decision in the opposition proceedings. In the opinion of the court, the compulsory licence action filed in parallel by Gilead also did not justify a stay of the proceedings.

In its judgment, the Düsseldorf Regional Court paid special attention to the relationship between the objection of disproportionality under Section 139 (1), sentence 3 of the Patent Act and the action for compulsory licensing under Section 24 (1) of the Patent Act.

As a result, the court resolutely established the subsidiarity of the objection of disproportionality vis-à-vis a compulsory licence action (in the same manner as Kühnen, *Handbuch der Patentverletzung*, 14th edition, chap. D, marginal No. 560). Even before the amendment of the law, the court argued in the same line in its judgment of March 9 2017 – 4a O 137/15 (see also the concerns voiced in McGuire, *Stellungnahme zum zweiten Patentrechtsmodernisierungsgesetz*, p. 13).

According to the court's reasoning, Gilead, as the trustee of its patients' interests, could reasonably be expected to bring a compulsory licensing action primarily before relying on the objection of disproportionality. Consequently, due to the subsidiarity of the objection of disproportionality, the court held that Gilead could not invoke the objection of disproportionality.

The aim of the court when formulating this strict subsidiarity principle was to prevent the circumvention of the requirements for compulsory licensing actions under Section 24 of the Patent Act and to ensure the jurisdiction of the Federal Patent Court.

The Düsseldorf Regional Court reasoned that only the Federal Patent Court has the technical expertise to deal with the technical issues relevant under Section 24 of the Patent Act. The infringement courts, which do not have technical expertise, therefore cannot guarantee the competency required in the context of injunctive relief.

Although Gilead's objection of disproportionality was already dismissed based on subsidiarity, the court additionally pointed out that the necessary requirements for the objection of disproportionality were not met in the present case due to Gilead's conduct. The court highlighted that in the context of the comprehensive balancing of interests – required by Section 139 (1), sentence 3 of the Patent Act – not only third-party interests but also the conduct of the patent infringer have to be taken into account.

The court held that the patent infringer's conduct is of high relevance because it may not "simply hide behind third-party interests". "The patent infringer's conduct must evidence their serious effort to protect patients' interests," the court stated. "Accordingly, especially in the case of vital medicines, the infringer must choose the least risky strategy to protect patients' interests. That means that he must seek alternative solutions and, if this is not possible due to regulatory requirements, engage in serious negotiations with the patent holder to obtain a licence."

The Düsseldorf Regional Court acknowledged that third-party interests are affected, because certain groups of patients are dependent on Gilead's challenged products due to the lack of alternative medicines. However, the court did not consider these third-party interests to be sufficient to support the objection of disproportionality, because Gilead had not made adequate efforts to obtain a licence.

The court held that sufficient efforts on the part of the infringer require that it first seek a licence on reasonable commercial terms before pursuing the grant of a compulsory licence. Bad faith negotiations, which merely intend to delay the legal dispute or which are carried out in anticipation of a price reduction due to the non-exclusivity of the licence, are insufficient.

The court also noted that the failure to initiate summary proceedings regarding compulsory licensing proceedings under Section 85 of the Patent Act also indicated a lack of serious effort on the part of Gilead.

Consequences of the judgment of the Düsseldorf Regional Court

The judgment of the Düsseldorf Regional Court counters concerns previously expressed in the relevant literature that the new objection of disproportionality would lead to a 'small compulsory licence' and the dilution of the right to injunctive relief for patent infringement.

The court also highlighted that the patent infringer's conduct – in particular, its serious effort to obtain a (compulsory) licence – must be considered when conducting the comprehensive weighing of interests required by Section 139 (1), sentence 3 of the Patent Act.

According to the Düsseldorf Regional Court, companies cannot simply invoke patient interests in infringement proceedings without pursuing further action to actualise those interests. Rather, they must make efforts to obtain a commercial licence and, if necessary, even bring an action for the grant of a compulsory licence.

Once these criteria are fulfilled, it remains to be seen to what extent the disproportionality objection will be of significance to ensure use of the patent for a transitional period, as envisaged by the legislator.

From a dogmatic point of view, the Düsseldorf Court's reasoning regarding the subsidiarity of the objection of disproportionality vis-à-vis a compulsory licensing action is persuasive. As the patent holder and the alleged patent infringer act upon the protection of patients' interests, it is convincing to require the patent infringer to take active steps in the form of (compulsory) licensing requests before considering granting them (temporary) use of the patent via the objection of disproportionality.

However, under certain circumstances, the court's reasoning regarding the subsidiarity of the objection of disproportionality and the trusteeship of the alleged infringer for their patient's interests leads to a problematic outcome. In the opinion of the Düsseldorf Regional Court, patients' interests take second place to the patent holder's interests if the alleged infringer has not sufficiently fulfilled its role as a trustee, even though patients' interests might be severely affected.

Patients' interests are thus directly dependent on the infringer's conduct to secure their interests. Given that the affected patients' interests are also protected by the German Basic Law, this understanding is debatable.

As the new wording of Section 139 (1), sentence 3 of the Patent Act expressly evidences, third-party interests are relevant legal interests and, as such, their effective protection has to be ensured.

Although the refusal of a compulsory licence may seem appropriate in certain cases due to the conduct of the infringer, applying an identical standard in the context of injunctive relief could be highly detrimental to third-party interests. This is especially problematic if third-party interests concern vital or systemically relevant products.

Affected patients will have no possibility of preventing or mitigating the risk, because they will neither be aware of potential patent infringements nor will they have the realistic possibility to influence the infringer to take active steps for their protection at an early stage of potential patent infringement. Thus, there is a risk that the criteria formulated by the court will be detrimental to patients' interests in certain instances, counteracting the legislator's intent.

The dependence of third-party interests on the infringer's conduct, as held by the Düsseldorf Regional Court, will certainly cause further discussions (see, for example, the statement on the draft law of the Second Act to Simplify and Modernise Patent Law by Fabian Hoffmann, judge at the Federal Supreme Court, published on February 19 2021).

It is also likely to prove difficult to derive corresponding rules for practice from the judgment. In particular, the question arises as to when the alleged infringer may seek a (compulsory) licence and, conversely, how long it may rely on its non-infringement and/or legal validity objection to obtain a dismissal of the action.

As a consequence of the judgment of the Düsseldorf Regional Court, the alleged infringer faces a catch-22 situation and has to assess whether to let sleeping dogs lie. If it makes an early effort to obtain a licence, the patent holder may interpret this as an acknowledgement of the possibility of infringement and initpateniate legal proceedings.

While the reasoning of the court seems practicable in cases of clear patent infringement, concerns will surely arise in cases where the actual infringement of the patent is unclear.

GREECE

Greek court applies doctrine of equivalents in numerical range

Patrinos & Kilimiris

Constantinos Kilimiris

While the doctrine of equivalents is well established as a legal theory in Greece, the number of decisions applying this is still not very large. In view of the above, any new decision is a welcome addition to building the respective Greek case law and clarifying the criteria applicable.

In this context the Athens First Instance Single Member Court was recently called to decide on a preliminary injunction (PI) application by an originator pharmaceutical company holding a patent protecting a pharmaceutical formulation, which was claimed on the basis of

its excipients and its load of active pharmaceutical ingredients (API) presented in a numerical range. The claim expressly excluded two excipients.

The generic product at issue differed in that its API load slightly exceeded that of the patent claim and contained, in its coating, one of the excipients excluded in the claim.

While there was no issue of literal infringement, the court was asked to decide whether the above differences in the generic product were sufficient to avoid infringement under the doctrine of equivalents.

The court's decision

The court ruled that the generic products at issue perform the same function, are directed to the same patients, and have the same therapeutic effect as the patented products.

Furthermore, it was held that the fact that the generic products' API were outside the claimed range was an insubstantial differentiation since they were still well within the tolerance generally accepted by the regulatory authorities and substantially achieved the same therapeutic effect.

Finally, as regards the different excipient in the generic formulation, the court held that this was also an insubstantial differentiation since it was contained in the coating of the tablet, which, according to the decision, is a non-functional element that did not affect the release of the API, the therapeutic effect, or the overall function of the invention.

In summary the court found that the differentiating features were obvious and equivalent variants of the claimed features that did not place the generic product at issue outside the scope of the claims.

Apart from being another decision applying the doctrine of equivalents in Greece, this decision is also important because the court held that even numerical ranges in patent claims should not be determined by their strict verbal sense but, like any other claimed feature, can be interpreted taking into account the perception of the person skilled in the art considering the patent description as well as the regulatory bodies' practice.

LAOS

Lao customs expands border measures to protect IP rights

Tilleke & Gibbins

Sukontip Jitmongkolthong and Saithong Rattana

Every country has its own customs measures in place to monitor goods crossing its borders. These measures are implemented by customs departments and other government agencies that facilitate international trade by checking shipments and collecting taxes on goods that enter and leave the country.

Laos is one of the many countries that have sought to create a favourable environment for operators to export, transit, move, and store goods. In addition to tax collection duties, the Lao customs department also has measures to safeguard IP rights and prevent unfair competition, including protections against the infringement of trademarks and copyright – measures that have been in place since 2011.

In 2022, Laos further improved its framework for enforcing IP rights through border measures against infringing goods. In February 2022, the government published new customs instructions that added industrial designs to the list of safeguarded IP rights for the Lao customs department. This means that an IP owner can now request the Lao customs department to take action on products infringing a protected industrial design under the customs border measures.

Procedures

The Lao customs department enables IP rights holders to protect their IP by allowing them to request the suspension of clearance for any goods imported, exported, or transiting in Laos on the grounds that a trademark, copyright, or industrial design is being or is likely to be infringed.

To be eligible for this protection, IP rights holders must submit a request for a declaration of ownership to the customs department. Once approved, the application is forwarded to the provincial and capital customs offices to serve as a reference for officers inspecting goods crossing the Lao border.

The declaration of ownership should be accompanied by the relevant written form for inspection and supervision of goods that are the subject of IP rights. Various other information and documentary evidence is also necessary before authorities can take action on the request.

Applications are submitted to the customs department, which is in the Ministry of Finance. After receiving the application, the department will inform the applicant as to whether the application is approved within 10 working days.

Once the application is approved, it will be forwarded to the provincial and capital customs offices for risk management and for use as a reference when officers inspect goods at the borders.

Customs protection is effective from the date of approval. The protection offered under the application is valid for two years and can be extended upon request.

Applicants can amend or add information to an application form throughout the protection of their IP rights through the customs department.

Getting help in specific cases

An applicant may also seek to enforce IP protection measures

against specific offenders by submitting a written request to the customs department, along with evidence of the suspected infringement and a cash security deposit or guarantee by a bank or other financial institution for LAK 10 million ($580) to compensate for any potential loss in the event there was no IP infringement.

After the department receives the application and necessary supporting materials, customs officers will conduct an inspection and temporarily seize the goods as requested by the IP rights holder.

Next, the customs officer will compare the information in the written customs declaration (e.g., names of the goods, brands, origin, value, packing, quality, transportation route, etc.) with the information in the IP rights protection database. If infringement is suspected, the customs officers have the right to detain the goods for 10 working days. The temporary suspension period may be extended if the applicant has provided evidence that dispute settlement or legal proceedings have been initiated in respect of the matter.

The customs officers may also choose to seize the goods and prosecute the infringer in accordance with the law.

Conclusion

When customs officers discover prohibited goods, the officers have the power to restrain or seize the goods, including any means of transport used in the commission of the customs offence. They also have the power to detain the persons involved, produce a case record, and hand over the suspect, together with the exhibits, to the Office of People's Prosecutor for prosecution.

This broad authority is why brand owners active in Laos can benefit greatly by collaborating with the customs department in fighting against infringement of their IP rights.

NEW ZEALAND

The Intellectual Property Office of New Zealand's importance in formulating patent practice

FB Rice

David Herman

New Zealand's Patents Act 2013 (the 'new Act') came into force on September 13 2014 and applies to the majority of patent applications filed in New Zealand. The changes in the new Act were intended to align New Zealand's patent laws more closely with those of significant trading partners.

The Intellectual Property Office of New Zealand (IPONZ) has often been required to interpret the new Act and its associated regulations to provide practice, procedural, and legal guidance in the absence of precedents. IPONZ achieves this through examination and opposition hearing decisions, its Patent Examination Manual, and consultation with stakeholders through various technical focus groups (TFGs).

Hearing decisions

In *Oracle International Corporation* [2021] NZIPOPAT 5, in interpreting the double patenting provisions of the new Act, the Assistant Commissioner clarified that a divisional application can include claims that overlap with the claims of an earlier accepted parent, provided that each claims distinctly different subject matter. Before this decision, IPONZ had applied a strict stance on what constitutes double patenting and raised objections against any overlap.

In *Ganymed Pharmaceuticals et al.* [2021] NZIPOPAT 6, the Assistant Commissioner clarified that a double patenting objection could be overcome by surrendering or amending the earlier application or patent. Before this decision, IPONZ had adopted a strict interpretation of the regulations where the subsequent fate of the first accepted application was not considered relevant and the accepted claims permanently set in place the claims for assessment of double patenting.

In *Intervet International v Merial* [2017] NZIPOPAT 12, in granting an extension of time to file a counterstatement in revocation proceedings, the Assistant Commissioner clarified the meaning of the phrase "exceptional circumstances" in the context of the new Act and regulations as "unusual, out of the common run", which was a much more lenient interpretation and arguably practical outcome for New Zealand patent applicants. In a rare occurrence, this decision was appealed to New Zealand's High Court, which agreed with IPONZ, stating at [37]: "It is difficult to imagine in the area of procedure relating to patent applications and patent proceedings that anyone is better placed to assess what is "unusual" than the experienced Commissioner or Assistant Commissioner."

In *CNH Industrial Belgium* [2018] NZIPOPAT 7, the Assistant Commissioner clarified that patent applicants wishing to amend the specification during examination no longer need to provide a specific statement of support setting out the parts of the original specification that support each and every proposed amendment. Rather, such a statement is only required if the applicant relies on the amendment finding support in the original specification. This interpretation of the regulations relaxed the support required for amending patent specifications.

Patent Examination Manual

The Patent Examination Manual sets out IPONZ's practices under the new Act and associated regulations, and includes commentary on relevant case law from the hearing office and courts. It is updated regularly and provides valuable and detailed guidance to applicants on how to navigate various sections of the new Act and its associated regulations. Many of these updates are the result of extensive consultation with stakeholders through various TFGs.

Technical focus groups

IPONZ has implemented TFGs for client representatives to provide feedback on proposed practice and policy changes or any updates to the Patent Examination Manual following any new precedents developed by IPONZ, including the decisions highlighted above.

Instead of updating practice and policy in a vacuum, IPONZ actively engages with stakeholders through the TFGs to ensure that any proposed changes in examination practice are consistent with IPONZ's hearing decisions. Additionally, the notes from each TFG meeting are published by IPONZ and provide guidance to patent applicants as to potential changes in examination practice.

Critical role in creating precedents

For various reasons, cases heard before IPONZ are rarely appealed to New Zealand's High Court. Therefore its decisions clarifying or interpreting the new Act and its associated regulations will often set critical precedent shaping New Zealand's patent practice. This highlights the importance IPONZ plays in formulating patent practice in New Zealand.

With the new Act still in its infancy at less than ten years old, we can expect that IPONZ will continue to be required to interpret New Zealand's patent law to shape practice and policy, especially in the absence of New Zealand court decisions.

SOUTH KOREA

Saving grace: Korean Supreme Court clarifies declaration timing of pre-filing disclosures

Hanol IP & Law

Min Son

South Korea allows a one-year grace period for pre-filing disclosures by inventors or applicants so that these disclosures are not regarded as prejudicial prior art in terms of novelty and inventiveness (Article 30 of the Patent Act).

In Korea, this grace period system has evolved over time. The law opened the door to all types of disclosures except for patent publications in Korea or foreign countries (as of March 3 2006), extended the duration from six months to one year (as of March 15 2012), and added procedural flexibility by allowing later claiming of the grace period such that it does not have to be made at the time of patent filing (as of July 29 2015).

Before all these changes, some portion of patent applications had to be rejected when they failed to comply with the procedural requirements, which appear quite stringent from the present perspective.

The Korean Supreme Court took another step forward in 2022. Without changing the law itself but through the interpretation thereof, it was declared that a divisional application can claim the benefit of the grace period (that the parent application could have claimed) even if the parent application had not claimed the same benefit (Supreme Court Decision 2020Hu11479, August 31 2022).

Facts and case history

In this case, the applicant did not claim the grace period for the prior disclosure (his master's thesis published around August 2014) at the time of filing the parent application on December 23 2014. The Examiner at the Korean Intellectual Property Office (KIPO) rejected the parent application for lacking novelty and inventiveness over the applicant's thesis.

Since the parent application was filed before the enforcement date (July 29 2015) of the amended provision of the Patent Act, which allows for a chance to amend defects in claiming the grace period during the prosecution, there was no option to amend the procedural defects in response to the Examiner's rejection.

Given the situation, the applicant filed a divisional application claiming the grace period within the allowed timeframe, and then withdrew the parent application. However, KIPO did not acknowledge the claimed grace period, and the divisional application was ultimately rejected for lacking novelty and inventiveness. Despite the applicant's appeal, the Intellectual Property Trial and Appeal Board affirmed the Examiner's rejection, as did the Patent Court.

The Supreme Court's decision

However, the Supreme Court expressed a different view on the matter, and concluded that even though the grace period had not been claimed in the parent application, in view of the purpose of the relevant provisions, it is reasonable to interpret that the divisional application can enjoy the benefit of the grace period based on 'its' (i.e., the divisional application's) filing date if:

- The procedures for claiming the grace period had been duly observed in the divisional application; and
- The parent application had been filed within 12 months from the prior disclosure date.

In this decision, Hanol IP & Law believes that the Supreme Court properly recognised the essence of the divisional system of Korea. In this jurisdiction, the applicant can file divisional applications for any subject matter that was included in the original application, even if the examiner has not issued a rejection for lack of unity of invention.

If, in the parent application, the applicant was not interested in pursuing the subject matter that had been pre-disclosed by the applicant, there would have been no need to claim the grace period. But if the applicant changes their mind later to have patents directed to those subject matters, it was probably not the lawmakers' intention to block the patenting of such subject matters only because the applicant did not pursue them from the beginning, by prohibiting claiming of the benefit at the later divisional stage.

Final remarks

Fortunately, under the present law, there are ample opportunities to amend defects in claiming the grace period during the prosecution, even if the claiming procedure was mistakenly missed at the time of filing. However, if the Patent Cooperation Treaty or Korean filing date is before July 29 2015, this option is not available. Instead, filing a divisional application can be an alternative in view of the Supreme Court's decision in August 2022.

This case is meaningful because it shows that even if the old law applies, a missed claiming procedure can be remedied by filing a divisional application claiming the grace period, as long as the original application was filed within the one-year grace period.

TAIWAN

Taiwan's IP and Commercial Court v ordinary courts

Saint Island International Patent & Law Offices

Sumin Lai

In Taiwan, the IP and Commercial Court (formerly the Intellectual Property Court) is vested with jurisdiction over first instance and second instance civil actions arising out of IP rights. However, the jurisdiction of this nature is not exclusive. In order for the IP civil actions to be heard as concentrated as possible by a specialised court, there is a so-called 'principle of preferential jurisdiction'.

Under this principle, the IP and Commercial Court has priority over ordinary courts to exercise jurisdiction, and ordinary courts should transfer IP civil actions to the IP and Commercial Court, with the exception of the following two scenarios:

- Where the two parties have both expressly agreed that an ordinary court has jurisdiction over the case (consensual jurisdiction); or
- Where the plaintiff files an action with an ordinary court and the defendant fails to raise any objection to the jurisdiction (implied consensual jurisdiction).

In practice, there has been a general consensus that the principle of preferential jurisdiction applies to first instance IP civil actions. However, there were divided opinions regarding the IP and Commercial Court's jurisdiction over the second instance cases, particularly the cases which were accepted and tried by district courts of first instance based on consensual or implied consensual jurisdiction.

Article 19 of the Intellectual Property Case Adjudication Act originally stipulated that "… any appeal against a ruling rendered by the first instance court on an intellectual property case *may* be lodged with the Intellectual Property Court..."

In 2014, this was amended to read "[a]ny appeal against a ruling rendered by the first instance court on an intellectual property case shall be lodged with the Intellectual Property Court having jurisdiction."

Since it is not explicitly stated in the amended stipulation that the IP Court has exclusive jurisdiction over appeals against court rulings, some judges took the position that appeals from district courts should be heard by the High Court having jurisdiction, while others opined that such appeals should be filed with the IP and Commercial Court regardless of the parties' consent to have the appeal heard by the High Court.

In 2019, the Supreme Court rendered ruling no. 381 articulating its view on the appellate jurisdiction of the IP and Commercial Court over second instance cases. The Supreme Court referred to Article 19 of the Intellectual Property Case Adjudication Act as the main legal basis and made the following observations:

Article 19 of the Intellectual Property Case Adjudication Act was amended on June 4 2014 to read "[A]ny appeal against a ruling rendered by the first instance court on an intellectual property case shall be lodged with the Intellectual Property Court having jurisdiction."

In the legislative reasons for the amendment, it was clearly indicated that "[A]t present, the first instance IP civil actions are not subject to the exclusive jurisdiction of the Intellectual Property Court". If such actions are brought under the jurisdiction of ordinary courts, they would likewise be heard and adjudicated by specialised IP units in district courts. In order to unify legal opinion, appeals against rulings of district courts on the IP civil actions 'should' be heard by the specialised IP and Commercial Court. However, it is unclear in the language of Item 2 of the current Article 19 regarding the court having jurisdiction over appeals against rulings of district courts. Therefore, an amendment to Item 2 of said article is being considered to avoid ambiguity or controversy.

As shown above, although the amended Article 19 does not specifically include the word 'exclusive', it is sufficient to recognise from the legislative intent that only the IP and Commercial Court has substantive exclusive jurisdiction over appeals against first instance rulings on IP civil actions so as to achieve the aim of unifying legal opinion. Therefore, consensual or implied consensual jurisdiction is not applicable to second instance cases.

Between 2020 and 2022, the High Court rendered three rulings on the jurisdictional issue following the Supreme Court's interpretation of Article 19 expressed in ruling no. 381.

Of the three rulings, ruling no. 699 rendered in 2020 relates to a civil action for breach of contract regarding the transfer of high temperature dyeing machine patent technology; ruling no. 56

rendered in 2021 relates to a civil action for monetary damages, in which a former managerial employee was accused of taking out the product design, customer information, contract and manufacturing order of the machine of the company without permission and setting up a new company to profit from making the same machine; and ruling no. 185 rendered in 2022 relates to a civil action for monetary damages involving a dispute over trade secrets in an LED module display technology cooperation agreement. In all of the three cases, the Taiwan High Court held that the IP and Commercial Court should have jurisdiction over appeals from the district courts.

In view of these recent rulings, there seems to be a tendency in current practice to divide the IP civil actions to exceptionally give ordinary courts jurisdiction only over the first instance actions, while the IP and Commercial Court substantively has exclusive jurisdiction over IP civil actions in the second instance.

It remains to be seen how and to what extent the relevant stipulations will be amended and whether the amendment would substantially affect the jurisdictional issue in practice.

TURKEY

Turkish Court of Cassation's decision on search and seizure orders strengthens IP owners' position

Gün + Partners

Zeynep Seda Alhas
and Atahan Erkul

Pursuing the criminal complaint route against counterfeits is highly effective in Turkey, yet several criminal courts are hesitant in granting search and seizure warrants.

The most problematic courthouse in this respect has been that of Istanbul. This courthouse is important because its jurisdiction covers significant locations for brand owners, such as Grand Bazaar, Taksim, and Tahtakale. The criminal courts of the Istanbul courthouse have been rejecting search and seizure warrant requests, without any concrete and satisfactory justification, for quite some time.

Gün + Partners, among many other law firms involved in the practice, has been collaborating with non-governmental organisations and holding several high-level meetings with the Turkish Ministry of Justice to attempt to resolve this long-standing, arguably incorrect, practice of certain courts.

An important precedent

On September 23 2022, the Istanbul courthouse's 4th Criminal Court accepted a complainant's objection against a decision of the 3rd Criminal Court rejecting a search and seizure warrant request as usual, based on a recent non-published decision by the Turkish Court of Cassation (CoC), and granted a search and seizure warrant.

The CoC's decision was issued by the 19th Criminal Chamber with Nos. 2020/1872 and 2021/318 on January 21 2021 and constitutes an important precedent for brand owners.

In the conflict, the brand owners filed a joint criminal complaint before the Istanbul Public Prosecutor's Office and the specialised intellectual property (IP) prosecutor requested a search and seizure warrant from the criminal court on duty. The evidence in the file was a test purchase from the infringer with a receipt and an expert opinion confirming the counterfeit nature of the purchased goods.

The Istanbul 3rd Criminal Court rejected the search and seizure request, merely stating that "there is no objective and convincing evidence to create reasonable doubt as to the crime, which is necessary for granting a search and seizure warrant". The court also stated that the expert opinion could not be deemed to be objective because it had been brought before the court by the complainants.

Upon the complaint's objection, the 4th Criminal Court took over the matter. While accepting the objection and granting a search and seizure warrant, it referred to the above-mentioned decision by the CoC and found the submitted evidence sufficient, and determined the presence of reasonable doubt for allowing a raid to be conducted at the address, which led to the seizure of hundreds of counterfeits and the prevention of a crime.

In the conflict subject to the CoC's precedential decision, the complainants could not file a receipt or an invoice confirming where the goods were purchased from, but they filed an expert report confirming the counterfeit nature of the samples purchased without receipt, and an undercover police investigation was ordered by the local Prosecutor's Office, which also confirmed continuing sales at the related address.

The CoC's chamber determined that an expert report could be taken into consideration as sufficient evidence for 'reasonable doubt' because the undercover police investigation's minutes also supported the complainants' claims. The chamber also specified that the brand owners would not file complaints against sellers of genuine products, because that would not be in line with the ordinary course of life.

Final thoughts

The reasoning of the CoC's decision was well prepared and emphasised that complaints by brand owners shall be evaluated in a broader manner because it would not be logical to expect them to file complaints to seize originals. This does not mean that the criminal courts should not seek further evidence, such as receipts and police investigation reports, to back up

the complaints of brand owners, but direct and unreasoned refusal decisions of the criminal courts are no longer to be accepted without question.

Even though brand owners might have had unpleasant experiences during criminal proceedings in recent years, this decision by the CoC has already started to have an effect. Indeed, Gün + Partners has managed to obtain several search and seizure warrants from the Istanbul courthouse. This also shows how important it is to seek a better IP ecosystem and practice.

VIETNAM

Assessment process remains an obstacle in copyright enforcement in Vietnam

Tilleke & Gibbins

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In copyright disputes in many countries around the world, experts who can provide professional opinions based on their deep expertise in specific fields play a very important role. It is the same in Vietnam when copyright disputes are brought to court.

Judges and court staff may have almost no knowledge in specific areas of settlement such as fine arts, music, or computer programs. For this reason, they focus only on the legal aspect of the cases; however, the legal aspect can only be considered on the basis of analysis from experts, commonly known in Vietnam as 'assessment' (or expert opinion).

Assessment is essential

For copyright disputes that are resolved in court, except in cases where the behaviour is very clear, a court order only occurs when there are assessment conclusions. The legal basis for considering assessment conclusions as an important source of evidence can be found in the 2005 Law on Intellectual Property, as amended in June 2022, and its subordinate legal documents.

However, the particular importance of assessment is not shown in legislation but rather in practice, through the fact that the courts and procuracies attach great importance to these assessment conclusions and treat them as necessary – sometimes even compulsory – documents from which they make judgments and rulings.

It is rare for a court to express any opinion on the contents of an assessment conclusion, and rarer still for a court to make a judgment or ruling that is contrary to the conclusion. Thus, it seems that assessment conclusions, though originally intended as reference points only, are becoming decisive documents in many cases. In other words, the party that wins the assessment conclusion is much more likely to win the case.

Obstacle to be resolved

For better or worse, assessment has become very important in the process of settling a case. However, the problem is that not all objects can be assessed, and there are not sufficient experts to provide reliable assessment conclusions for every case.

In addition, the procedures of assessment are very complicated and can be time-consuming. Often the courts are powerless to resolve cases because they depend on the assessment agency.

In an ongoing copyright dispute with regard to a musical work, for example, though the case was first accepted by the Ho Chi Minh City People's Court in July 2018, it still had not been heard by the court four years later. One of the reasons for the delay is that the court had to wait for an assessment conclusion, which was not issued until June 2022.

In another case heard by the Binh Duong People's Court in August 2022 with regard to a dispute over a computer program, the most bothersome issue was the valuation of the infringed software. In this case, although the original amount claimed was nearly $1.5 million, the final amount of compensation accepted by the court was only around $200,000, because the court and the related parties could not find a common language – or a capable expert to provide an assessment conclusion – with regard to the valuation of the infringed object.

In practice, when it comes to cases related to assessing the amount of damages – something holders of infringed copyrights are always keen to have assessed by experts, to give the courts a basis for making judgments and rulings – experts in general are often very confused in reaching conclusions.

This is due to many different reasons; for example, it may be partly because the damages caused by an IP object tend to be relatively vague, or because the expert does not have much experience or training in assessing damages. Sometimes, even when there is clear enough evidence to enable the expert to reach an assessment conclusion (for example, there is a price quote on the licensing value of a work publicly displayed on the internet or in an offer for sale by the copyright holder), the expert still feels uncomfortable shouldering this responsibility in making their assessment.

It is clear that there are too many issues regarding assessment in copyright disputes that need to be resolved. Suggestions for improvement have come from many directions: the courts need to be more independent in making their judgments; more assessment centres should be established rather than just one under the Copyright Office of Vietnam; or independent experts should be accepted in legal proceedings. These are all options Vietnam should explore in the near future.