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IP & Life Science News

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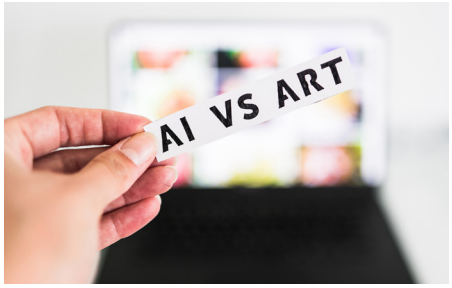
AI artists & human artists battle in court:

Lawsuits filed against generative AI

Generative AI models have received significant hype the last couple of months to a degree that might only be rivaled by previous once-in-a-decade technological shifts, such as the advent of the smartphone and the internet.

In a previous issue of Accura's IP & Life Science News (available here), we wrote about generative AI models that are able to generate images from a written prompt. As detailed in that article, a number of potential copyright issues encircle such generative AI models which create ripe grounds for unpredictable legal situations and in turn for legal conflicts.

Recently, litigation has been brought against Stability AI (in the US and the UK), Midjourney and DeviantArt (in the US), who are creators of generative AI models, due to potential copyright issues. The plaintiffs claim that the generative AI models violate copyright law by scraping artists' work from the web for use as input data without consent.



These new conflicts bring to life some of the real world legal and ethical issues that may arise from such generative AI models and emphasize the importance of understanding the legal ramifications in this area.

In brief: Artists' class-action suit

A class-action lawsuit has been filed by three artists (as class representatives) against Stability AI, DeviantArt, and Midjourney for their use of the AI software product Stable Diffusion created by Stability AI. The lawsuit was filed on 13 January 2023 at the District Court of San Francisco.

The plaintiffs claim that the defendants infringe their copyright directly and vicariously by using their artwork as training data to produce "new" images from written prompts. According to the lawsuit:

"*The plaintiffs and the Class seek to end this blatant and enormous infringement of their rights before their professions are eliminated by a computer program powered entirely by their hard work.*"

Furthermore, the plaintiffs claim inter alia violation of the Digital Millennium Copyright Act, unfair competition and breach of contract.

In relation to the lawsuit, a representative of Stability AI has told Insider (the magazine) that the allegations "represent a misunderstanding of how generative AI technology works and the law."

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In brief: Getty Images cases

In addition to the artists' class-action suit, Getty Images – one of the world's leading creators and distributors of digital content – has also filed a lawsuit against Stability AI in the UK (January 2023) and in the US (February 2023) for violating its intellectual property rights. The lawsuits were filed with the High Court of Justice in London and the District Court of Delaware.

Getty Images states the following in its US complaint of 3 February 2023:

"Upon information and belief, Stability AI has copied more than 12 million photographs from Getty Images' collection, along with the associated captions and metadata, without permission from or compensation to Getty Images, as part of its efforts to build a competing business."

Aside from copyright infringement, Getty Images also claims inter alia trademark violation and unfair competition.

Accura comments

We had to wait less than 2 months following our previous article on legal uncertainty in relation to generative AI models for several lawsuits to be filed.

The subject matter of the class-action and the Getty Images cases might be very similar, but there is a difference in the focus of the complaints. Whereas the class-action appears broader in focus and draws on general occupational harm caused to artists and betrayal of artists' communities, the focus of Getty Images' complaint is use of its images, for which the company was not compensated.

In this regard, Getty Images' complaint seems to pack some punches in the fact that Getty Images has previously licensed its images and various data to other companies which have developed generative AI models. Also, Getty Images claims trademark infringement on the basis that Stable Diffusion has included the Getty Images watermark in some of its generative works.

We will continue to monitor further developments in this area.

NFTs & the Metaverse: Where are we now ...?

In previous editions of our newsletters we have focused on one of the most ground-breaking trends of the time, namely NFTs and the metaverse. In a previous edition we provided our beginner's guide to understanding NFTs. We have also written about how trademarks for virtual products and NFTs should be classified and what needs to be considered when choosing an online platform and when preparing license agreements relating to NFTs and the metaverse here.

In this edition, we once again dive into the remarkable and fast growing world of NFTs

Verdicts in the first NFT cases

The first verdicts regarding the relationship between NFTs and trademarks have been handed down since we last wrote about them in our newsletter.

The Juventus case

The most notable of these was rendered by an Italian court close to the end of 2022. The case concerned the question of whether online sale of digital football cards as NFTs constituted an infringement of the football club Juventus' trademark rights, since several of the club's players were pictured on the cards wearing the black and white striped Juventus' club wear. The Italian court found that the sales of both the NFTs and that digital content that was associated with them (the digital football cards), infringed Juventus' well-known trademark.

The Italian judgement is interesting as the court clearly distinguishes between NFTs and the associated digital content, as evident from the fact that the injunction on marketing and sales included both the digital football cards as well as the NFTs. The NFTs were thus covered by the injunction, despite the fact that they are essentially only proof of ownership on a blockchain which does not possess a visual identity.

The Birkin case

In addition to the cases in the EU, the first two US cases on IP infringements and NFTs have been presented before the American courts.

One of these cases, which we have previously addressed in this newsletter, concerns the design of the well-known "Birkin Bag" from French fashion house Hermès. This design was offered as 100 NFTs created by artist Mason Rothschild.

Hermès filed a lawsuit against Rothschild claiming, among other things, trademark infringement. New York's Federal Court has just rendered judgment in the case, finding that Rothschild's use of the designation "MetaBirkin" and use of the "Birkin" bag design with NFTs constitute trademark infringement and harms Hermès well-know "Birkin" trademark and design. Rothschild's defense, that it was not commercial exploitation, but that the use was a personal and artistic form of expression covered by the First Amendment, was rejected by the court stating that the First Amendment protection applies only to expressive works, and not to explicitly misleading works. Hermès was awarded around USD 130,000 in damages.

The NIKE case

The second case concerns a number of NIKE sneakers offered as NFTs and sold on the online trading portal StockX. The case concerns the question of whether NFTs might be classified simply as a form of "digital receipt", which verifies the purchase of the physical shoes to which the NFT pertain, or whether the NFTs must be considered as virtual products themselves, which therefore constitutes a violation of NIKE's trademark rights. This lawsuit is pending.

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Both American cases are representative of the fact that NFTs, despite still being in the technology's infancy, has given rise to significant legal conflicts which i.a. involves some of the world's most well-known fashion brands and the fact that NFTs challenge the existing legislation.

New classification from EUIPO

The EU is already seeing a rip in activity in relation to trademark applications related to NFTs and the metaverse. On 1 January 2023, the European trademark authority EUIPO's 12th edition of the Nice Classification entered into force, which for the first time includes NFTs and virtual goods.

EUIPO treats NFTs as unique digital certificates registered in a blockchain, which authenticate digital items but are distinct from those digital items. It is not sufficient for a trademark applicant to use the term non-fungible tokens (NFT) on its own, as the type of digital item authenticated by the NFT must also be specified.

With regard to virtual goods, these are treated as digital content or images. For a trademark related to virtual goods to overcome the clarity/precision barrier, the trademark must be specified by stating the content to which the virtual goods relate (e.g. downloadable virtual goods, such as shoes).

Trademarks related to NFTs and virtual goods must be registered in class 9 (software etc.).

As for the assessment of whether a trademark is eligible for registration in class 9, the administrative practice of EUIPO seems to reflect that a trademark must be compared not just to other virtual goods/services but also to goods/services provided on the physical market.

One of the more attention worthy attempts of trademark registration related to NFTs was Burberry's application for trademark registration of its famous checked pattern for use on web3/metaverse-related goods/services including NFTs. EUIPO partially refused Burberry's application on grounds of lack of distinctive character. EUIPO found that the pattern was not essentially different from patterns used by other brands in the physical world and therefore refused registration of the pattern for "virtual apparel" in class 9. In this regard, it was noted that "the consumer's perceptions for real-world goods can be applied to equivalent virtual goods as a key aspect of virtual goods is to emulate core concepts of real-world goods". Registration was, however, accepted for use in relation to "downloadable skins" in class 9. For now, it is unclear whether Burberry is going to appeal EUIPO's decision.

A scalding hot market (still)

The latest numbers from EUIPO reveal that 1,157 applications related to NFTs have resulted in registered trademark and design rights in 2022. This is a testament to the fact that the burgeoning market for NFTs continues to grow by a rapid pace. We expect the clarity that comes with the updated Nice Classification will result in a higher number of rights registrations and further fuel the NFT market.

The development of the metaverse also indicates that it will soon be necessary for IP rights holders to a greater extent consider how they optimize for securing their rights in the digital arena. In a 2022 report, the multinational American investment bank Citi predicted that the metaverse has the potential to reach 5 billion users and a market economy of between 8 and 13 trillion (!) dollars in 2030. There are thus strong signs that the metaverse is going to impact the lives of most people with the consequence that many of the legal matters, that exists in physical life – including IP rights matters – will follow the users to their digital existence in the metaverse.

We will continue to monitor developments closely and inform about the latest news via our newsletters.

Third party litigation funding – the next big trailblazer?

Embarking on litigation or arbitration can be a daunting step - one which is inherently risky, and comes with significant expense, even in the strongest of cases.

The financial risk alone will keep some actors from taking legal steps or engaging in legal proceedings, but the concept of litigation funding could provide a useful solution to this issue.

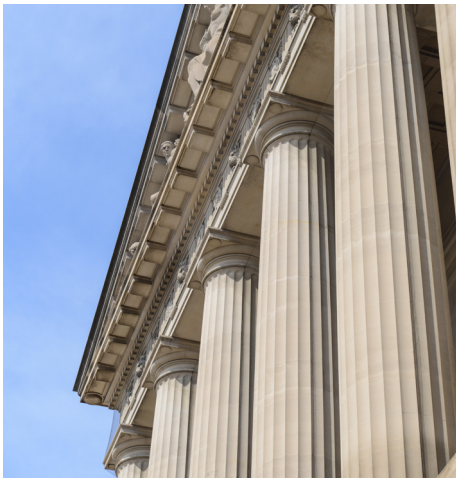
Not least for potential parties to proceedings before the upcoming Unified Patent Court, litigation funding may be worth looking into, especially due to the high costs associated with proceedings before the Court and the initial lack of predictability surrounding the new system.

What is litigation funding?

Litigation funding is a rapidly growing practice where a third-party investor, also known as a litigation funder, provides financial assistance or resources to a party in a legal dispute (most often the claimant), covering some or all legal expenses relating to the legal proceedings, thus severely reducing the party's risks of financial loss. In return, the litigation funder receives a share of the potential profits such as costs and damages gained from the legal dispute.

Litigation funding is typically non-recourse, which means that if the party supported by the litigation funder loses the case, it is not required to repay the funder. Instead, the funder assumes the risk of loss and only receives a return on investment if the party is successful in its case. Access to this kind of funding can provide parties with the necessary financial means to initiate legal proceedings which might not otherwise be brought before the courts (or to put up a worthy defence), due to the severe costs often associated with being a party to legal proceedings. Even parties with sufficient financial resources to engage in legal proceedings may benefit from litigation funding, for example by preventing legal proceedings from influencing their cash flow or to mitigate the risk associated with engaging in legal proceedings.

The concept of litigation funding has been around for decades, but it has gained significant attention in recent years due to the increasing costs of legal representation and the lengthy and uncertain nature of legal proceedings.



Litigation funding in Denmark

As for now, litigation funding is not specifically regulated under Danish law, but the Danish Supreme Court has (at least indirectly) accepted such form of financing. Specifically for arbitration proceedings, the Danish Institute of Arbitration has adopted into its Rules of Arbitration a provision requiring the parties involved to inform the Secretariat, the Arbitral Tribunal and the other parties of the identity of any third party, which has entered into an arrangement regarding funding of any costs in relation to the case and under which it has an economic interest in the outcome of the case (the Rules of Arbitration article 20(4)).

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Litigation funding at the Unified Patent Court

Litigation funding can be a useful tool within most types of dispute resolution cases, and not least when it comes to intellectual property infringement litigation as IP rights often constitute key commercial assets for the involved companies and such cases therefore involve high stakes as well as severe damage claims.

Specifically within patent infringement litigation, the soon to come Unified Patent Court could be fuelling for an emerging market for litigation funding in Europe. Introducing a new system in which a patentee may bring an action and obtain damages in a single litigation venue covering most of Europe and a market of over 300 million people, the Unified Patent Court may become an attractive litigation forum, competitive to the flourishing US litigation funding market.

Further, with value-based court fees reaching up to as much as 325.000 EUR, litigators looking to bring actions before the UPC may have good reason to engage a litigation funder in the process.

With the court being ready to operate from 1 June 2023, litigation funding has the potential become a real trailblazer with Europe's patent litigation scene.

Accura comments

Despite its many benefits, litigation funding is not without its challenges. One of the primary concerns is the potential for conflicts of interest between the funder and the plaintiff's attorney. Some argue that litigation funders may exert undue influence over the plaintiff's legal strategy, particularly if the funder has a financial interest in the outcome of the case. Another challenge is the lack of regulation of the litigation funding industry.

In conclusion, litigation funding can provide a valuable means for parties to access the legal system and engage in legal proceedings. However, it is important to carefully consider the risks and benefits of litigation funding.

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Biosimilars can be used without the Medicines Council's prior assessment

The Danish Medicines Council recently announced that it is abandoning the requirement to apply for the Council's assessment before putting into use biosimilar medicinal products. This announcement is based on the European Medicines Agency's **statement as of September 2022** that biosimilars approved in EU are considered interchangeable with their reference biosimilar medicinal product or with an equivalent biosimilar.

As a result of the Council's change of practice, from now on, a biosimilar medicinal product can be taken directly into use without first applying for the Danish Medicines Council's preceding assessment of the biosimilar. The only requirement is that the biosimilar has the same indication and administration route as another medicinal product (or an equivalent biosimilar) that has already been recommended by the Council.. If a treatment guideline already exists, biosimilars meeting this requirement will automatically be included in the next Amgros tender and classified in the subsequent recommendation.

The new practice by the Danish Medicines Council is a significant change, as it will accelerate the process of bringing biosimilar medicinal products into the Danish market to the benefit of patients.

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Sustainability and environmental topics can now form part of courses for HCPs

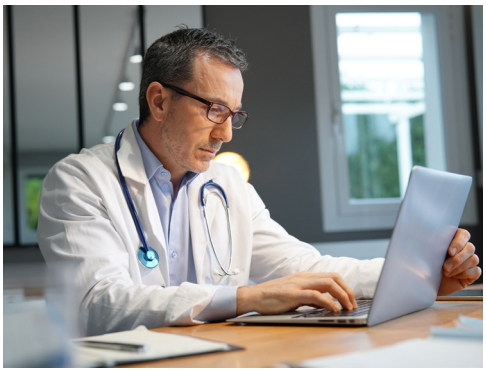
Environmental and sustainability issues and solutions are becoming increasingly more relevant for both the pharmaceutical industry and healthcare professionals (HCPs). For the same reason and in the wake of a recent decision from the Appeal's Board of the Danish Ethical Committee for the Pharmaceutical Industry (ENLI), will soon update its guidance to the Promotion Code to reflect that pharmaceutical companies may now offer HCPs training and professional information in environmental and sustainability related topics.

In the referenced appeal case, ENLI's Appeals Board found that under specific circumstances environmental topics can be included on the agenda at a professional event for HCPs hosted by a pharmaceutical company. This is an extension of the current spectrum of topics allowed under the Code of Practice on Promotion etc. of Medicinal Products Aimed at Healthcare Professionals ("the Promotion Code").

The provision of professionally relevant information and training to HCPs

Pharmaceutical companies may provide or offer HCPs professional training, education and healthcare related information in the form of payment of direct expenses in connection with a professional relevant course, conference, training etc., in which the HCPs participate or arrange, cf. Section 13.1 of the Promotion Code. In these activities, pharmaceutical information or other information relevant for the HCP-participants must be included. This requirement as to the content of the given activity is known as the professionalism requirement, pursuant to which the activity must have professional and special healthcare content.

This means that at training events for HCPs, the agenda may only include topics which are of a 100 % professional nature. This includes for example medical presentations on specific diseases, disease areas, medicinal products and methods of treatment. Courses on health economics is only considered in compliance with the requirements, if they focus on therapy- or medication-oriented issues (in contrast to more political aspects thereof, which are not permitted). On the other hand, non-healthcare specific courses will generally not be permitted, which includes i.a. courses also offered to other professional groups such as financial control, organizational development, leadership and computer courses.



The Decision of the Appeals Board and the expansion of professionalism requirement

In the specific case before ENLI's Appeals Board, a pharmaceutical company had requested ENLI's Investigator's Panel's pre-approval of a meeting or symposium for HCPs, where the environmental consequences of using greenhouse gas in inhalation treatment was a topic on the agenda. No brand specific medicinal products were to be mentioned and the inhalators were only to be mentioned in respect of their carbon footprint.

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With reference to the Promotion Code and the requirement that training etc. must be professionally relevant, ENLI's Investigator's Panel did not grant the requested pre-approval. The Investigator's Panel's decision to reject pre-approval was then appealed to ENLI's Appeals Board.

Upon reviewing the case, the Appeals Board decided that the requirement that training etc. must be professionally relevant should be expanded to include training activities related to environmentally relevant topic of relevance to the healthcare sector, provided 3 specific conditions would be fulfilled:

- Firstly, the purpose of including the topic in the training event must be to increase HCPs' understanding of how climate effects may affect the work in the healthcare sector.
- Secondly, no specific medicinal products can be mentioned in connection with topics of the aforementioned kind.
- Thirdly, the topic in question may not directly or indirectly be characterized or understood as advertisement for medicinal products.

Following the Appeals Board's decision to expand the requirement of professionalism to also include topics concerning environmental and sustainability related issues, ENLI's guidance on the Promotion Code will soon be updated. Pharmaceutical companies may, however, already now begin to include such topics on the agenda at training events for healthcare professionals.

Accura's comments

ENLI's recent expansion of the requirement of professionalism underlines that environmental and sustainability issues are becoming increasingly relevant – also for the healthcare sector and its stakeholders such as HCPs. ENLI demonstrates with the decision to be prepared to amend its interpretation of the Promotion Code to keep up with the developments of the healthcare sector and the world around it.

If you are interested in more information on this topic, we also recently published a newsletter on use of environmental claims in pharmaceutical advertising, which you can retrieve here.

Extension of the transitional periods in MDR and IVDR

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The European Parliament and Council recently adopted the Commission's proposal to extend the transitional periods of the medical device regulatory framework ("MDR" and "IVDR"[1]).

The initiative is a reaction to the potential threat to the continued availability of certain medical devices as notified bodies are struggling to keep pace with the number of applications for conformity assessment under the new MDR and IVDR.

To avert the risk of shortage of medical devices, notified body capacity and manufacturer preparedness, a number of amendments to the MDR and IVDR have been adopted.

Key amendments include:

- Differentiated extensions of the transitional period to obtain a conformity assessment under the new rules:
  - For high-risk medical devices (most class IIb and III devices), the transitional period is extended until 31 December 2027.
  - For medium and low risk medical devices (class I and most class II devices), the transitional period is extended 31 December 2028.
  - For class III custom-made implantable medical devices, the transitional period is extended until 26 May 2026.
- The possibility of extending the validity of certificates issued according to the old regulatory framework given that the following conditions are met.
  1. *The medical device has not undergone significant changes in its design and/or intended purpose.*
  2. *The medical device does not present any unacceptable risk to health and safety.*
  3. *The manufacturer has, before 26 May 2024, undertaken the "necessary steps" to obtain certification under the new MDR and IVDR (such as adaption of its quality management system and submission and/or the notified body's acceptance of application for conformity assessment).*
- Removal of the "sell of" provisions of MDR and IVDR, which permitted medical devices certified under the old framework to be placed on the market only until 26 May 2025.

The above extensions will become effective as soon as the adopted text has been published in the Official Journal of the European Union.

[1] Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on in vitro diagnostic medical devices

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