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DECEMBER 2023

BRIEFS

MVS TURNS 100

We are excited to announce that McKee, Voorhees & Sease, PLC will be celebrating its 100th Anniversary in 2024. We thought we would kick it off by showing our new logo in this issue of the MVS Briefs. Be sure to stay connected to MVS for updates throughout the year as we continue our 100 year celebration.

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Luddites, Lawyers, Illustrators:
Embrace AI as a Tool

CASSIE J. EDGAR
Partner, Chair, Regulatory Law Practice Group and Co-Chair,
Data Privacy and Cybersecurity Practice Group

The Unhappy Painter, by Theodor Hosemann, 1843, illustrating a painter as a victim of technology, made obsolete by photography.

Artificial intelligence (AI) is disruptive and will change the way we create and innovate – similar to disruption from the printing press, the camera, Photoshop, and gene editing. Use of any tool does not remove the need for a human brain and human experience behind the tool's usage and implementation, and does not inherently preclude IP protection.

Looking at art as one concrete and controversial application, AI is revolutionary, enabling artists and inventors to rapidly create new and unique digital works through platforms such as DALL·E 2. In many ways, AI can be viewed as a new medium for creating art, in addition to paint, pencils, and pixels. Just as artists have always used new tools and techniques to create their work, AI allows artists to explore new forms of creativity and expression. Outside of artistic applications, AI technology is also helping inventors to create new and innovative products- as hot topic technologies of genetic sequencing, 3D printers, and gene editing have enabled in the past.

AI, like any other tool, is only as good as the person using it. A paintbrush, a camera, or a CRISPR enzyme is just an instrument. It is the artist and inventor who puts it to use to create an original innovative work. The user must provide input and direction, and refine and implement the results into a final product.

When the camera was first invented in the early 19th century, it faced resistance and backlash from painters and other artists. The invention of photography was a revolutionary technology changed the way people created and viewed art. Many painters expressed concern because photography could easily and quickly capture a moment or a scene that was difficult to replicate in paint, and some saw photography as a cheap and easy way to produce art that would take away the value of traditional art forms. This is discussed in detail by Aaron Hertzman in his article "Can Computers Create Art?" in which it is noted that "At first, photography, like AI, was seen by many as non-artistic, because it was a mechanical process. Some saw photography as a threat and argued against its legitimacy."

In addition, Hertzman notes that many artists were dismissive of photography and saw it as a threat to "real art." Historical accounts indicate that some painters felt that the new technology threatened the financial stability of their profession, and that photographers would take over the market, making it difficult for painters to sell their works. Traditional artists saw photography as a sort of cheating, a tool that created art without the need of skill or training. Sound familiar? We have been here before.

One challenge to widespread adoption of new technologies, including AI, is clarity on how existing works and new creations will be protected and commercialized. Challenges which are already being discussed broadly and in some cases litigated, are IP protection and **regulatory requirements** related to the use of AI as a tool. There are active copyright protection cases related to usage of **artist materials** and **software** as training sets for AI, as well as IP litigation and patent prosecution matters regarding use of AI for innovations such as **drug discovery**.

The U.S. Patent and Trademark Office is actively engaging with stakeholders in AI and emerging technologies. "The USPTO plays an important role in incentivizing innovation in critical technologies such as AI and other emerging technologies (ET) (e.g., quantum computing, synthetic biology, blockchain, precision medicine, and virtual reality), and maximizing these innovations' widespread impact to enhance our country's competitiveness, economic prosperity, and national security, and to solve world problems." **(Kathi Vidal, Under Secretary of Commerce for Intellectual Property and Director of the USPTO)**. The USPTO is holding a series of stakeholder meetings in order to inform future changes to fulfill this role. (see e.g. **https://www.uspto.gov/initiatives/artificial-intelligence** for extensive references and upcoming meetings on this topic).

As has happened with previous disruptive technologies, both IP law and regulatory frameworks will need to adjust and case law will clarify the metes and bounds of these systems as they apply to AI.

Technology will continue to advance, and it will be important for policy makers and attorneys to find solutions which protect innovations generated with the assistance of AI tools while respecting existing IP rights. The challenges that AI brings to the table are not entirely new, as similar challenges have been faced with other new technologies including photography, genetic sequencing, and gene editing. But as with any new technology, there will be social license debates regarding adoption, and laws and regulations which will need to be adapted to ensure AI is used responsibly and in a manner that protects the rights of artists and creators.

INTANGIBLE ASSET PROTECTION— IT'S YOUR MONEY

GLENN JOHNSON
Attorney Practicing in Commercial, Employment, Intellectual Property Law and Litigation

Dated back to its identified origins in John Heywood Proverbs (1546), variations on shutting the barn door after the horse has bolted apply equally well to trade secret and confidentiality law.

The United States Patent and Trademark Office has estimated the value of intellectual property in the United States to be approximately $5 trillion dollars – further estimating the yearly loss of such IP at $250 billion. Once gone, it cannot be recaptured.

As 2024 approaches, it presents a good opportunity for all business enterprises to employ a simplistic and realistic assessment of valued intangible assets. Trade secrets are an integral part of overall protection of such assets, but only if proper forethought is given to the legal scheme required to protect such assets.

Taking a few hours to evaluate your protection strategy may be worth great amounts of money in the future. Such evaluative steps include:

1. Identify what is truly important to your business operations, including what would be harmful if it fell into the hands of your competitors. With this, determine if any of the pillars of intellectual property (IP) law might provide some measure of protection – patents, trademarks, copyrights, trade secrets.
2. If none of the IP protections fit the bill, or even if they do, also consider the use of simple contract law. Having employees, consultants and vendors sign confidentiality agreements which provide sufficient specificity as to the confidential/trade secret information to be protected. If one breaches the contract, then you don't have to establish much of the legal proofs required under trade secret law, but you do have to quantify and prove what damage flows from the breach. At the very least, this process may allow for a relatively quick judicial intervention providing an injunction preventing the dissemination or use of the confidential information by the offending party.
3. To attach "trade secret" types of protection, take the following steps with the goal of providing reasonable protections to the intangible assets:

a. ***Labeling:*** Mark paper and e-files as "CONFIDENTIAL/TRADE SECRET."

b. ***Segregation:*** Build a paper/electronic moat – Move hardcopy confidential/trade secret documents to a separate filing drawer or cabinet having a locking system and limit the distribution/access to the key.

c. ***Agreement:*** Have all employees execute a confidential agreement wherein each acknowledges the existence and importance of confidential and trade secret information to the operations and vitality of the company.

d. ***Restriction:*** Segment the assets based upon use and/or valuation and identify those employees/positions to which access may be granted, thereupon restricting all others from access.

e. ***Exit:*** Present all departing employees with notice of the need to return all confidential information and not to use or supply such information to their new employer or any other 3rd party.

f. ***Notice:*** Deliver notice to new employers that their new hire (your former employee) had access to confidential information, and that such information should not be divulged to or used by the new employer.

Quoting the February 4, 1735 issue of the Pennsylvania Gazette, *"An ounce of prevention is worth a pound of cure."*

Developments Protecting Children's Data Privacy

SARAH M.D. LUTH
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The past two years have seen a wave of new state legislation focused on child online privacy and safety. A recent poll from the University of Michigan C.S. Mott Children's Hospital found that the top three child health concerns for parents were screen time, social media, and internet safety. It is no surprise that, in an era dominated by digital interactions, concerns over data privacy have intensified, particularly regarding vulnerable populations like children. As the mechanisms for violation of child privacy continue to grow, so too do the digital harms facing children.

Children, with their limited understanding and control over their personal information, are increasingly exposed to potential risks from applications, websites, and other platforms that track their data intentionally or inadvertently. Engagement with social media platforms such as TikTok and Instagram represent significant venues for the disclosure of a child's personal information and surveys show that participation with social media can have a negative impact on a child's mental health.

The legal framework for safeguarding children's privacy in the United States is a patchwork framework of overlapping federal and state laws. The federal Children's Online Privacy Protection Act (COPPA) is a foundational child privacy law in the United States. However, COPPA, which was passed in 1998 and amended in 2013, has long been in need of an update to better protect children on the internet. Although Congress discussed modifications to COPPA, and a "COPPA 2.0" was proposed, such efforts to update the law have stalled thus far.

States have increasingly attempted to fill in the gaps left by COPPA. Near the end of 2022, California passed the California Age-Appropriate Design Code (CAADC), which significantly expands the scope of, and protections created by COPPA. Compliance obligations under the CAADC include (a) the use of age-estimation obligations; (b) configuring all default privacy settings to offer a high level of privacy; and (c) conducting data protection impact assessments. Earlier this year, Illinois passed the country's first law protecting child influencers, ensuring financial compensation for minors (those under 16 years old) who are featured in certain types of online content. Although the Illinois law functions as an amendment to the state's existing child labor laws,

it reflects the growing conversation about whether children can consent to their photos or videos being posted and whether such content violates a child's privacy.

However, the constitutionality of these new state laws is being increasingly challenged. Federal district court judges in Texas and Arkansas issued injunctions against newly passed "age verification" laws, raising questions about their constitutionality. Similarly, in California, a federal judge granted a preliminary injunction against the CAADC, on grounds that the act likely does "not pass constitutional muster." The Arkansas Social Media Safety Act would have required a minor to seek parental or guardian consent to create a social media account and would have required social media platforms to verify the account holder's age. Texas' HB 1181 would have restricted minors' access to adult content online and required platforms with such content to verify the age of its users. These laws were challenged on similar grounds, namely a violation of First Amendment rights.

Whether and which state laws survive legal challenges will be something to watch in 2024. Regardless of the outcomes in California, Texas, and Arkansas, in the absence of a comprehensive U.S. privacy law—or even updates to existing federal child privacy laws—other states will likely continue to pass new laws protecting child content creators and child privacy in the coming months.

Seeking Antibody Claim Breadth Post-*Amgen v. Sanofi*

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Senior Patent Agent

Monoclonal antibodies (mAb) like HUMIRA®, KEYTRUDA®, STELARA®, DUPIXENT®, and OPDIVO® command a market estimated at $178.5 billion in 2021. Up until 2017, the broadest patent claims available to protect such mAb's described the therapeutic target that the mAb could bind and thus covered mAb which competitors could be obtain by time consuming, costly, but nonetheless routine experimentation.

The United States Court of Appeals for the Federal Circuit ("CAFC") effectively ended this long-held patent examination practice in deciding that such functionally limited mAb claims did not meet the "written description" requirement of 35 USC 112 (Amgen v. Sanofi, CAFC, 872 F.3d 1367 (2017); Cert denied; 139 S.Ct. 787 (2019). The U.S. Supreme Court also struck down broad mAb claims drawn to what a mAb binds as lacking enablement (Amgen Inc. v. Sanofi, S. Ct., No. 21-757 (2023)). The CAFC and Supreme Court's decisions in the Amgen Inc. et al. v. Sanofi cases leave few options for patent applicants seeking to exclude competitors who can obtain functionally equivalent mAb with by simply using the same or equivalent therapeutic target and well-established procedures.

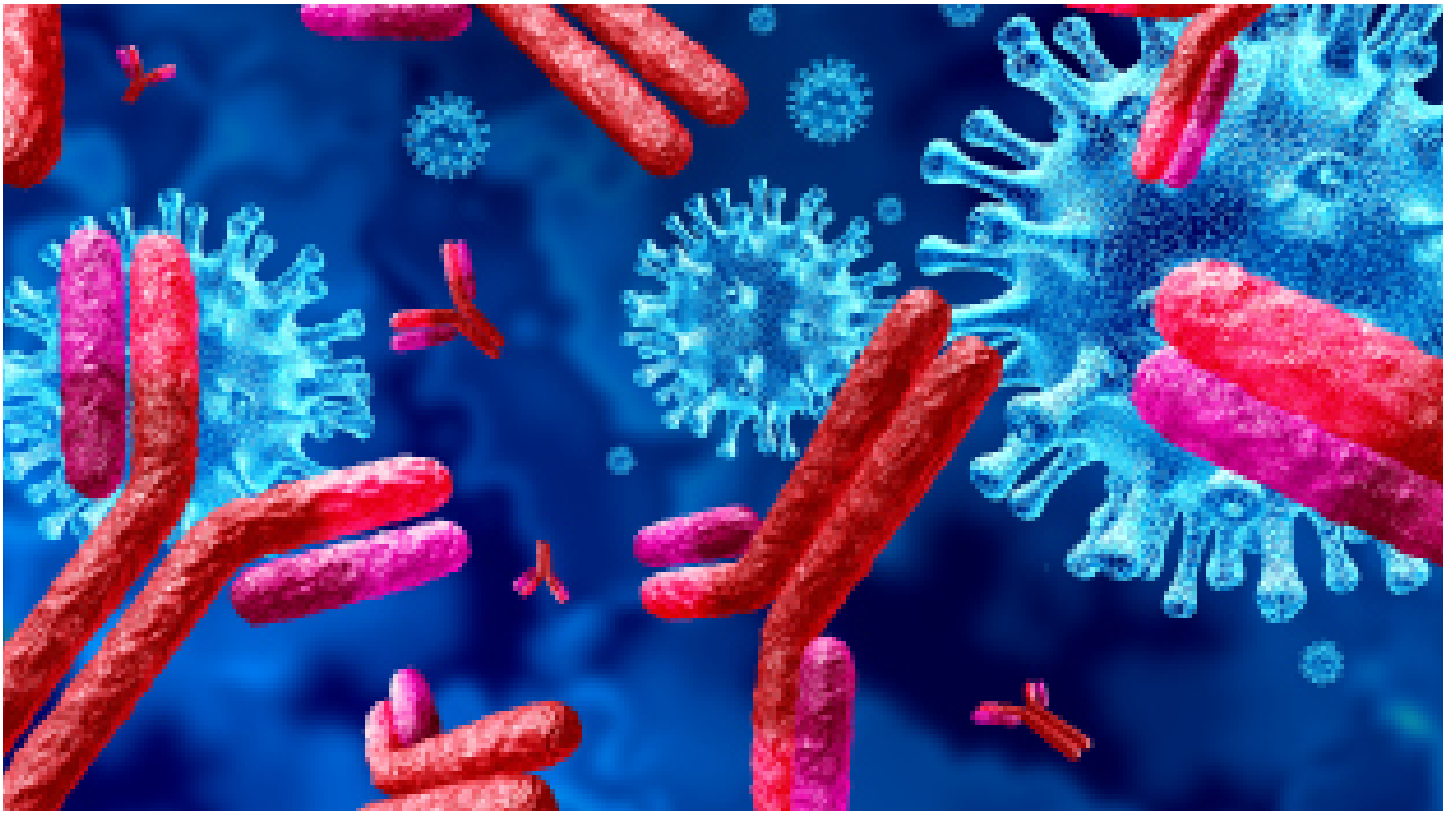
Not surprisingly, an informal search of U.S. patents granted since the Supreme Court's decision in May of 2023 finds that the vast majority of granted mAb claims are structurally limited to at least three distinct and very short "complementarity determining regions" (CDRs) which bind to the disease target to provide therapeutic activity. These CDRs comprise very short biological peptide sequences which can have as few as three amino acids and as many as 18 amino acids. Such "CDR limited" claims do not exclude use of routinely obtainable mAb with wholly distinct CDRs which bind the same antigen and may not even exclude use of a competitor's mAb comprising a single amino acid substitution in one of the CDR's.

One interesting exception to the "CDR" only claim rule is seen in U.S. Patent No. 11,773,159 to Merck Patent GmbH, which granted on October 3, 2023. Merck's '159 patent is drawn a single chain antibody where the CDR1 sequence is limited to a single three amino acid sequence, a CDR2 sequence which can have "up to three amino acid differences within the amino acid sequence of AISGSGDDTYYADSVKG (SEQ ID NO: 380)" (i.e., the CDR2 sequence), a CDR3 sequence which can have "up

to three amino acid differences within the amino acid sequence of RRGLYYVWDSNDYEN (SEQ ID NO: 522)" (i.e., the CDR3 sequence), and which "binds at least to human IL-17A." The '159 patent claims would thus read on any single chain antibody which binds to human IL-17A, has the three amino acid sequence the CDR1, has any one of 19 different amino acids at 1, 2, or 3 positions within the 17 amino acid-sequence of CDR2, and/or has any one of 19 different amino acids at 1, 2, or 3 positions within the 15 amino acid-sequence of CDR2. The '159 Patent identified at least five members of this family of single chain antibodies which bind the same region of the human IL-17A target where all 5 members of the family have the claimed three amino acid CDR1 sequence. Two members of this family had a single amino acid change at two distinct positions in the claimed CDR2 sequence, two members of the family had the same single amino acid change at the same single amino acid position in the claimed CDR3 sequence, and one member had three amino acid changes in three contiguous residues of the claimed CDR3 sequence. These claims were not rejected during prosecution for failure to meet the written description or enablement requirements.

The CAFC and Supreme Courts Amgen v. Sanofi decisions have clearly put a stop to expansive functionally based mAb claims based on what the mAb binds. Nonetheless, we can anticipate that patent applicants will continue to explore avenues to claw back some mAb claim breadth beyond simple CDR sequences. One such approach is to claim the binding element via a "means plus function" claim which "shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof" (35 USC 112(f)). An example of a "means plus function" clause would read "a means for binding (X)" where the claim would be limited to the binding means set forth in the application and "equivalents thereof." The USPTO's position that certain mAb "means plus function" claims fail the written description requirement will soon be decided by the CAFC (In re Xencor Case: 23-2048).

For now, applicants should continue to track mAb claims granted by the USPTO and considered by the courts post-Amgen v. Sanofi to understand what claim breadth can be obtained and what experimental data is needed to support such breadth. Applicants should also track any guidance documents that the USPTO sends to the Examiners on the patentability of various types of mAb claims. While there is no foreseeable return the broad functional mAb claims, a path to mAb claims which are not limited to specific CDRs should emerge.



Navigating Plant Breeders' Rights: Implications of UPOV 78 and UPOV 91

BRIAN D. KEPPLER, PH.D.
Patent Agent

The International Union for the Protection of New Varieties of Plants (UPOV) is the intergovernmental organization established by the International Convention for the Protection of New Varieties of Plants, adopted in Paris in 1961. The Convention was subsequently revised in 1972, 1978 and, most recently, in 1991. While the 1978 Act of the UPOV Convention ('UPOV 78') replaced the prior versions, the 1991 Act of the UPOV Convention ('UPOV 91') and UPOV 78 continue to coexist.

Currently, 76 countries and two intergovernmental organizations (African Intellectual Property Organization and European Union) are members of UPOV, with most adhering to UPOV 91. However, several countries, including Argentina, Bolivia, Brazil, Chile, China, Colombia, Ecuador, Italy, Mexico, New Zealand, Nicaragua, Norway, Paraguay, Portugal, South Africa, Trinidad and Tobago, and Uruguay still adhere to UPOV 78. The adherence to UPOV 78 in these countries presents a unique set of challenges for breeders looking to secure international protection for their varieties. UPOV 78 and UPOV 91 differ in significant ways that may impact the strategy of breeders seeking protection across different countries.

UPOV 91 offers a more robust and expansive set of rights to breeders than the UPOV 78 predecessor. For example, UPOV 91 includes rights over harvested material and products made directly therefrom, which may be critical when the value of the variety extends beyond the propagating material. In contrast, countries adhering to UPOV 78 may offer more limited control over the end products of the variety.

UPOV 91 broadens the scope of protection to all plant genera and species, unlike the more limited UPOV 78 that varies by country. For breeders seeking to protect varieties in countries under UPOV 78, they may find limitations in the types of plants that can be protected. This can influence decisions on where to prioritize filings, especially for those dealing with less common or unconventional plant species.

Another significant difference is the duration of protection. Under UPOV 78, the minimum duration of protection is 15 years from grant for most varieties and 18 years for trees and vines. UPOV 91 extends this

to 20 years for most varieties and 25 years for trees and vines, offering breeders a longer period to capitalize on their investments.

UPOV 78 generally recognizes farmers' privilege, allowing farmers to reuse seeds from protected varieties for further planting, while this is further restricted under UPOV 91. UPOV 91 does maintain a breeder's exemption, allowing breeders to use protected varieties for breeding and developing new varieties, but introduces limitations with the concept of Essentially Derived Varieties (EDVs). A variety is considered essentially derived if it is predominantly derived from an initial protected variety and retains the essential characteristics of that variety. This inclusion of EDVs in UPOV 91 extends protection to these new but closely related varieties. This lack of provision for EDVs under UPOV 78 means that breeders of the original varieties may have limited control over subsequent variations that are essentially derived from their creations. Overall, breeders enjoy more extensive rights over their varieties and their derivatives in UPOV 91, but this comes with stricter limitations on how these varieties can be used by other breeders and farmers.

Understanding the nuances between UPOV 78 and UPOV 91 is crucial for plant breeders seeking international protection. The choice of where and how to file for protection needs to be informed by these differences, which influence the extent of rights and enforcement capabilities. Navigating these complexities is key to effectively securing and leveraging plant variety rights in diverse international markets.

WHERE WE'LL BE

Business Record Book of Lists Unveiling
January 4, 2024 - Des Moines, Iowa

MVS will be attending

TechStars Startup Weekend
January 12-14, 2024 - Des Moines, Iowa

Cassie J. Edgar, Patent Attorney and Chair, MVS Regulatory Law Practice Group and Co-Chair, Data Privacy and Cybersecurity Practice Group

Sponsored by MVS

Women in AgTech Conference
January 21-22, 2024 - Glendale, Arizona

Cassie J. Edgar, Patent Attorney and Chair, MVS Regulatory Law Practice Group and Co-Chair, Data Privacy and Cybersecurity Practice Group

Cassie will be presenting

VISION Conference
January 22-24, 2024 - Glendale, Arizona

Cassie J. Edgar, Patent Attorney and Chair, MVS Regulatory Law Practice Group and Co-Chair, Data Privacy and Cybersecurity Practice Group

Cassie will be presenting

ASTA 63rd Vegetable & Flower Seed Conference
January 26-30, 2024 - Monterey, California

Heidi Sease Nebel, Patent Attorney and Chair, MVS Biotechnology and Chemical Practice Group

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Colorado State University Gene Editing Panel
February 1, 2024

Heidi Sease Nebel, Patent Attorney and Chair, MVS Biotechnology and Chemical Practice Group

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2024 AUTM Annual Meeting
February 18-21, 2024 - San Diego, California

Heidi Sease Nebel, Patent Attorney and Chair, MVS Biotechnology and Chemical Practice Group

Christine Lebron-Dykeman, Partner and Chair, MVS Trademark Practice Group,

Jonathan L. Kennedy, Patent and Litigation Attorney and Chair, MVS Litigation Practice Group

Glenn Johnson, Attorney Practicing in Commercial, Employment, Intellectual Property Law and Litigation

Kevin M. Kercher, Patent and Trademark Attorney in the MVS Mechanical-Electrical Practice Group

Gregory Lars Gunnerson, Patent Attorney in the MVS Mechanical-Electrical Practice Group

Melissa Mitchell, Patent Attorney in the Biotechnology and Chemical Practice Group

Brian D. Keppler, Ph.D., Patent Agent in the Biotechnology and Chemical Practice Group

Christine, Jonathan and Glenn will be presenting on February 19, 2024 on the topic of Plant Patent Enforcement Strategies.

Iowa Academy of Trial Lawyers Meeting
February 22-23, 2024 - Des Moines, Iowa

Jonathan L. Kennedy, Patent and Litigation Attorney and Chair, MVS Litigation Practice Group

Glenn Johnson, Attorney Practicing in Commercial, Employment, Intellectual Property Law and Litigation

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Iowa Biotech Showcase and Conference
February 28, 2024 - Ankeny, Iowa

MVS will be attending & sponsoring

Michigan State University Innovation Celebration
April 2, 2024 - Lansing, Michigan

Heidi Sease Nebel, Patent Attorney and Chair, MVS Biotechnology and Chemical Practice Group

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