OBLON

IP UPDATES

SEPTEMBER 18, 2023

USPTO UPDATES

U.S. Copyright Office Looking into Copyright and Artificial Intelligence

BY DAVID M. LONGO, PhD

On August 30, 2023, the U.S. Copyright Office announced a Notice of Inquiry and Request for Comments as part of "a study of the copyright law and policy issues raised by artificial intelligence ("AI") systems."

According to the Office, "purpose of this Notice is to collect factual information and views relevant to the copyright law and policy issues raised by recent advances in generative AI." The Office "intends to use this information to advise Congress by providing analyses of the current state of the law, identifying unresolved issues, and evaluating potential areas for congressional action. The Office will also use this record to inform its regulatory work and to offer information and resources to the public, courts, and other government entities considering these issues."

The Office is seeking to gather information on copyright policy issues impacted by AI, namely, "(1) the use of copyrighted works to train AI models; (2) the copyrightability of material generated using AI systems; (3) potential liability for infringing works generated using AI systems; and (4) the treatment of generative AI outputs that imitate the identity or style of human artists," and specifically "seeks public comments on these and related issues." To this end, the Notice presents 34 questions touching on AI and copyright, many of which are broken down into several sub-questions. The questions are designed to encourage comments by stakeholders and the public, and are loosely grouped under the topics of "general," "training", "transparency & recordkeeping," "generative AI outputs," "copyrightability," "infringement," "labeling or identification," and "additional questions about issues related to copyright."

The Notice is published in the Federal Register here:
https://www.govinfo.gov/content/pkg/FR-2023-08-30/pdf/2023-18624.pdf
Written comments are due October 18, 2023, and written reply comments are due November 15, 2023.

The Office also has a dedicated website, **www.copyright.gov/ai**, "to provide information about [its copyright and AI] Initiative, including planned events and opportunities for public engagement."

Revised PTAB Oral Hearing Guide Available

BY RICHARD D. KELLY

On August 31, the USPTO made available an updated Oral Hearing Guide. The updated Guide provides for:

- The addition of an all-virtual hearing option for America Invents Act (AIA) trials.
- Updated information on how the public may request to view a PTAB hearing, either in person or remotely.
- Clarification of procedures for submitting demonstratives for ex parte appeal hearings.
- Clarification on how parties may request pro hac vice admission.

The Guide is available **here**.

Director of the USPTO Discusses the Domicile Address Requirement

BY EVAN C. SMITH

The Director of the U.S. Patent and Trademark Office (USPTO) published a **blog post** on August 30, 2023, entitled "How the domicile address requirement advances our trademark anti-fraud efforts." This post discusses the new **examination guide** issued by the USPTO to clarify steps that examining attorneys must take when evaluating an applicant's "domicile."

In recent years the USPTO has seen an increasing number of fraudulent Trademark applications. Often these applications come from foreign entities which seek to evade the U.S. Counsel Rule which was enacted in 2019 and requires all overseas applicants to identify a U.S. licensed attorney as a representative. These fraudulent applications frequently utilize falsified U.S. street addresses and stolen attorney credentials to create the appearance that domestic counsel has been retained. Additionally, the USPTO has identified several U.S. attorneys who entered into business agreements with international trademark filing mills. These attorneys lent their names, signatures, and addresses to applications which they did not file; a direct violation of the USPTO's **Rules of Practice**.

The post outlines the intensified procedures for domicile review that have been enacted to combat fraudulent applications and trademark scams. Since 2019 the USPTO has issued 258 final orders for sanctions associated with the U.S. Counsel Rule which invalidated 18,789 applications and sanctioned 3,297 more. The post does not identify any changes to application procedure and legitimate applicants will have no additional responsibilities associated with filing. The USPTO notes that any legitimate applicant who fears for their personal safety due to the publication of their address may file a **Petition to the Director** to have their domicile address redacted. The Office seeks any ideas or suggestions for improving the USPTO's anti-fraud practices at **TMScams@uspto.gov**.

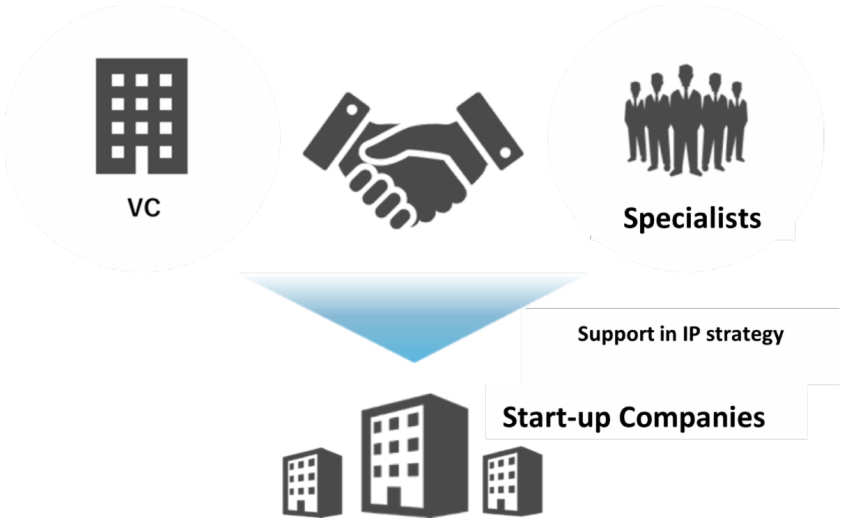
JPO UPDATES

VC-IPAS Is Going To Kick Off!

BY KASUMI KANETAKA

The JPO launched an IP community portal site "**IP BASE**" in December 2018. The portal was established as a part of supporting start-up companies. One of the goals in launching the site is to be a platform to connect both people who are related to start-up businesses and specialists working in the IP field.

Based on this portal, VC-IPAS (Venture Capital collaborating on Intellectual Property Acceleration program for Startups) is going to kick off in September 2023. This program supports start-up companies through VC to structure IP strategies by sending patent agents and attorneys to the VC for about six months.



There are ten VCs selected for this year's program. They are Archetype Ventures, ANRI, Senshu Ikeda Capital, QB Capital, LLC, Keio Innovation Initiative, Scrum Ventures, Tohoku University Venture Partners, Fast Track Initiative, Mitsubishi UFJ Capital Co., Ltd., and Innovations and Future Creation Inc. (MIRAI SOUZOU). They were chosen through the application processes between June 2023 and August 2023. The specialists will be sent to the VCs from September 2023 to March 2024.

Often, start-up companies and others face difficulties searching where and how to initiate constructing IP strategies and filing applications. Sending specialists in the IP field to VCs could motivate those companies to become more familiar with the IP field and utilize the system.

TRADEMARK UPDATES

Malwarebytes Off More Than it Can Chew: Labeling a Company's Software as "Malicious" and a "Threat" Gives Rise to False Advertising Claim Under Section 43(a)

BY BRIAN B. DARVILLE and CHRISTOPHER I. DONAHUE

In *Enigma Software Group USA, LLC. v. Malwarebytes, Inc.*, 69 F.4th 665 (9th Cir. 2023), the Ninth Circuit Court of Appeals reversed the district court's judgment dismissing Enigma Software's false advertising claim against competitor Malwarebytes based on Malwarebytes designating Enigma's software products "malicious" and a "threat."

"To show falsity under the Lanham Act, a plaintiff must allege that 'the statement was literally false, either on its face or by necessary implication, or that the statement was literally true but likely to mislead or confuse consumers.'" 69 F.4th at 671 (quoting *Southland Sod Farms v. Stover Seed Co.*, 108 F.3d 1134, 1139 (9th Cir. 1997)). The district court dismissed the false advertising claim ruling that Malwarebytes' statements labeling Enigma's software as "malicious" or a "threat" were non-actionable opinions not verifiable statements of fact.

The Ninth Circuit reversed reasoning that when a company in the computer security business describes a competitor's software as "malicious" and a "threat" to a customer's computer, that is more a statement of objective fact than a non-actionable opinion. It is actionable under the Lanham Act provided the other elements of a false advertising claim are alleged.

The Ninth Circuit also reversed the holding of a lack of personal jurisdiction and reinstated Enigma's claim for relief under New York Gen Bus. Law § 349. The Ninth Circuit also held that

Enigma's tortious interference with business relations claim should not have been dismissed. The panel affirmed the dismissal of Enigma's tortious interference with contractual relations claim because Enigma failed to identify a specific contractual obligation with which Malwarebytes interfered.

Judge Bumatay dissented, writing that Malwarebytes' statements flagging Enigma's software products as "potentially unwanted," a "threat," or "malicious" are subjective statements, not readily verifiable, which means they are nonactionable opinions protected by the First Amendment. Treating these statements as actionable statements of fact "sends a chilling message to cybersecurity companies – civil liability may now attach if a court later disagrees with your classification of a program as "malware." But we have neither the authority nor the competence to arrogate to ourselves regulatory oversight over cybersecurity." Judge Bumatay added that Enigma's failure to allege a misstatement of fact is also dispositive of its state law claims.

AI UPDATES

District Court Finds That Artwork Created Solely by AI is Not Eligible for Copyright Protection

BY SAMEER GOKHALE

The United States District Court for the District of Columbia recently held that artwork created by artificial intelligence (AI) is not eligible for copyright protection. In the Decision issued on August 18, 2023 as *Thaler v. Perlmutter*, D.D.C., No. 1:22-cv-01564, Judge Beryl A. Howell upheld the refusal of the copyright by the Copyright Office, which was the first court case in the country to find a boundary on legal protections for AI-generated artwork.

The case was brought by scientist Stephen Thaler, who is well-known in patent circles as bringing the "DABUS" case to jurisdictions all over the world in an attempt to establish that AI can be listed as an inventor. In this case, he was attempting to register a copyright for the art piece titled "A Recent Entrance to Paradise" which was generated by a computer system Thaler calls the "Creativity Machine." The Copyright Office denied the application on the basis that the work lacked the human authorship necessary to support a copyright claim. This case follows recently issued guidance from the Copyright Office on the copyrightability of works created with the assistance of AI, which found that only material produced by human creativity can be the subject of copyright protections since the term "author" is human specific.

Judge Howell, upheld the denial, finding that the record showed that the work was created absent any human involvement.

FEDERAL CIRCUIT UPDATES

Federal Circuit Determines Anticipation of Dependent Claims and Holds That Free Samples Do Not Support a Claim of Commercial Success

BY RICHARD D. KELLY and COLIN DOWNEY

The Federal Circuit affirmed the PTAB's decisions in IPRs 2020-00002 and 2020-00004 finding the claims invalid as being anticipated and obvious over asserted prior art. The claims were directed to a method of delivering a therapeutic dose of radiation to a patient, which involved the injection of a biodegradable filler in the area between the target organ and a nearby tissue to increase a distance between the organ and the tissue, and then injecting the radiation dose. The patentee, Incept, made a failed attempt to prove the secondary indicia of commercial success. Incept

argued that its data showed an approximate doubling year of product shipments, stating clear evidence of commercial success was presented and erroneously ignored by the PTAB. However, although the data included replacement units, free samples as well as sales, no breakdown between the categories was provided. Further the data was not sales but shipment data. Incept's expert asserted market share of 55% did not rely on contemporaneous market size data in the United States – instead, the data was based on a trial in the UK to estimate the number of prostate cancer patients who underwent radiation treatment, and extrapolated from that trial.

The PTAB found the data to be unconvincing of commercial success because it referred to volume shipped and not sold. The PTAB faulted Incept for not showing how volume shipped alone demonstrates commercial success based on sales as opposed to replacement units and free samples. Further, neither of Incept's commercial sale witnesses explained how the units shipped demonstrated commercial success in the context of the market as a whole.

There are many challenges to successfully using commercial sales as an indicia of non-obviousness and taking shortcuts here will only lead to disappointment.

The decision also took a broader view of what is required for determining anticipation. The CAFC determined that the prior art anticipated the claims, by describing the general qualities of the compositions. Further, the CAFC found the claims to be anticipated because the prior art compositions *could become* biodegradable and additionally be used as a space-filling device. Part of the reason why the Court took this broader approach as to what constitutes anticipation may be because the claims themselves were broad, or not sufficiently specific, in the recitation of these features. Finally, the CAFC found that the dependent claims failed along with the independent claim because the dependent claims were not separately argued, stating that merely mentioning the dependent claims within arguments for the independent claim is not sufficient for separate consideration. Read our full blog on the decision **here**.

Federal Circuit Reiterates What Constitutes a Motivation to Combine, a Reasonable Expectation of Success, and Unexpected Results in New Chemical Compounds

BY SARA PISTILLI

In *Sun Pharmaceutical Industries, Inc. v. Incyte Corporation*, on August 22, 2023, the Federal Circuit affirmed a Final Written Decision of the Patent and Trial Appeal Board (the Board) of an inter partes review (IPR) asserting the claims of U.S. Patent No. 9,249,149 (the '149 patent) as obvious under 35 U.S.C. § 103. The central argument was whether Sun's "octo-deuterated" ruxolitinib analog (CTP-543) and "tetra-deuterated" ruxolitinib analogs, arising from claim 7 of the '149 patent, were obvious in light of the prior art references presented by Incyte (Rodgers, Shilling, and the Concert Backgrounder).

In light of the prior art, expert testimony, and the similarity between the prior art compound and that of the '149 compound, the Court concluded one of ordinary skill in the art would have been motivated to deuterate ruxolitinib to alter the compound's pharmacokinetics. The Court concluded that the combination of Concert, teaching that deuterating a compound's metabolic hotspots for improved pharmacokinetics, and expert testimony, stating the identified tetra- and octo-deuterated analogs of '149 patent were the "most reasonable deuterated analogs", would have motivated one of ordinary skill to make the specific modifications claimed in the '149 patent. Although Sun argued that the Board had ignored the "unpredictable" nature of modifying ruxolitinib, the Court determined that the Board had sufficient evidence to conclude modification of ruxolitinib would result in reasonably expected superior pharmacokinetics based on Concert's teachings of deuteration leading to improved safety, tolerability, and efficacy. The Court furthered that "some unpredictability" was not enough to rebut a reasonable expectation of success, stating that only a degree of predictability, not absolute predictability, is needed. The Court also rejected Sun's arguments that the Board erred by failing to consider two objective indica of nonobviousness: (1) unexpected results and (2) long-felt need. The Court determined that these were not unexpected results because the clinical activity presented by Sun was "merely a difference in degree and not in kind." Although Sun argued that the octo-deuterated ruxolitinib analog "satisfied a long-felt need for an FDA-approved, evidence-based alopecia

areata treatment", the Court noted that the octo-deuterated ruxolitinib analog, however, had not achieved FDA approval, which the Court found sufficient to conclude that this long-felt need was not satisfied.

This case is a reminder of what constitutes a motivation to combine prior art, a reasonable expectation of success, and unexpected results when analyzing new chemical compounds. Read our full analysis **here**.

LIFE SCIENCES NEWS

FTC on Improper Orange Book Listings

BY RICHARD D. KELLY

The Federal Trade Commission on September 13 voted unanimously to issue a statement on listing patents in the Orange Book intended to dissuade pharma companies from listing ineligible patents (copy **here**). This statement is in reaction to the recent district court decision delisting a Jazz Pharmaceutical patent directed to risk mitigation since the listing did not comply with the listing requirements defined in 21 U.S.C. § 21 U.S. Code § 355(b)(1)(A)(viii):

the **patent** number and expiration date of each **patent** for which a claim of **patent** infringement could reasonably be asserted if a **person** not licensed by the owner of the **patent** engaged in the manufacture, use, or sale of the **drug,** and that—
(I) claims the **drug** for which the applicant submitted the **application** and is a **drug** substance (active ingredient) **patent** or a **drug product** (formulation or composition) **patent;** or
(II) claims a method of using such drug for which approval is sought or has been granted in the **application**.

Jazz listed a patent not directed to either the patents defined in (I) or (II) but rather to a computer system for mitigating risks. No claim was present directed to either the drug product or for an approved use. The result was that Jaz was able to delay FDA's approval of Avadel CNS Pharmaceuticals generic equivalent to Jazz's drug Xyrem. The FTC is seeking to prevent such listings where such listings "may be an unfair method of competition and violate the FTC Act."

For more information on the Jazz district court decision see our blog see blog post **here.**

In Re Cellect - ODP Defense Does Not Impact the Expiration Date of a Patent With Both PTA and PTE in the Absence of a Terminal Disclaimer

BY RICHARD D. KELLY

The Federal Circuit in *In re Cellect,* Appeals Nos. 2022-1293, 2022-1294, 2022-1295, 2022-1296 held that the earliest patent to expire in a series of patents subject to obviousness-type double patenting (ODP) controls, i.e., the PTA in the later to expire patents is lost and all patents are invalid for double patenting.

Cellect attempted to argue that the Judicial doctrine of ODP could not trump the statutory grant of PTA. This argument was rejected based on the difference in the language of 35 U.S.C. § 154, the PTA statute and 35 U.S.C. § 156. The Court rejected Cellect's argument that the USPTO's failure to make a double patenting rejection insulated the patents from invalidation for double patenting since Cellect was not put on notice of the issue. The failure of the USPTO to make rejections under these paragraphs does not preclude invalidation in litigation under these provisions. Cellect offered no compelling reason why § 101 should be any different.

What many of the commentators failed to note was the Court's discussion of the interplay between PTA and PTE in a patent having both extensions and a potential double patenting issue. On pages 16 and 17 of the slip opinion the Court explained that under § 156 the PTE is to be added to the end of the PTA *unless* a terminal disclaimer was filed. Since § 156 mandates that the PTE is to be added to the end of the PTA period, the presence of possible ODP does not impact the extension calculation which would involve adding the PTE period to the end of the PTA period in the absence of a terminal disclaimer. Thus, while the USPTO errs in not making a double patenting rejection, the PTE should not be affected for determining the expiration date. Read more **here**.

NEWSLETTER EDITOR: **GRACE KIM**