

IP UPDATES

DECEMBER 15, 2022

USPTO

[USPTO Announces Cancer Moonshot Expedited Examination Pilot Program](#)

BY GRACE KIM AND YUANYI (ALEX) ZHANG

The USPTO has published a **Federal Register Notice** announcing a new program: the Cancer Moonshot Expedited Examination Pilot Program.

Beginning on February 1, 2023, the new program expedites examination for a broad scope of technologies to prevent cancer and cancer mortality. Patent applications pertaining to the qualifying technologies will be accorded special status and reviewed earlier. The program is scheduled to run until either January 31, 2025, or the date by which the USPTO accepts a total of 1,000 grantable petitions, whichever is earlier.

The new program replaces the USPTO's Cancer Immunotherapy Pilot Program, which expedites examination for eligible patent applications pertaining to methods of treating a cancer using immunotherapy and terminates on January 31, 2023.



[Unified Patent Court – Start Date Extended Again](#)

BY RICHARD D. KELLY

The start date of the unified Patent Court (UPC) has been delayed again for two months. Originally slated to open on April 1, 2023, it will now open on June 1. The delay applies also to the “sunrise” period when patentees can opt out from the court’s jurisdiction and the date when UPC patents will issue.

The delay was caused by problems with users obtaining the smart cards to access the case management system, the CMS. This gives patentees more time to decide their strategy regarding the UPC and their existing patents. While the UPC has its advantages, it also has

[Patent Office Public Advisor Panel's 2022 Report](#)

BY RICHARD D. KELLY

The Patent Public Advisory Committee (PPAC) appointed by the Secretary of Commerce has nine voting members. The committee is statutorily responsible for reviewing “policies, goals, performance, budget, and user fees of the United States Patent and Trademark Office ... and advise the Director on these matters.” 35 USC 5. The committee also must prepare an annual report. This year’s report focuses on making patents accessible, predictable, durable, enforceable, affordable, and understandable patent rights. The need for predictability is a long felt need in the life sciences where the Federal Circuit’s unpredictability presents

disadvantages which patentees must evaluate regarding their portfolios especially regarding patents protecting their commercial embodiments. Patentees should not expect further delays given that the UPC confirmed that all other aspects of the launch are on schedule.

significant challenges in securing enforceable patent protection. A copy of the report is [here](#).

PTAB

[PTAB Reverses §101 and § 103 Rejections for Plant Extract](#)

BY GRACE KIM AND SARA PISTILLI, PHARMD.

On December 6, 2022, the Patent Trial and Appeal Board (PTAB) overturned a rejection of a claim to a plant extract based on patent ineligible subject matter (Appeal 2022-001062). The PTAB decision concludes that even if the individual compounds in a composition have the same properties as they have in a natural product such as the plant extract, and even if the composition has the same use as prior extracts, if the claimed composition has different amounts of the compounds and results in markedly different properties than the natural product, the composition is patent eligible under 35 U.S.C. §101. [Read more](#)



[PTAB Reverses Obviousness Rejection Based on Overlapping Ranges and Affirms Double-Patenting Rejection with Terminal Disclaimer](#)

BY GRACE KIM AND CHRIS TUINENGA, PH.D.

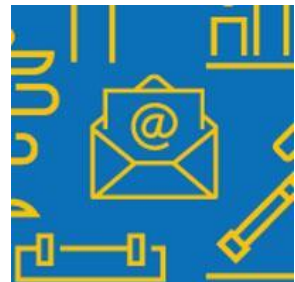
Colgate-Palmolive Co. appealed the Examiner's rejection of U.S. Application No. 15/530,725 (filed June 26, 2017). The Board's decision is a reminder that a prior art reference simply disclosing an overlapping range is insufficient for establishing a *prima facie* case of obviousness that requires making specific selections, where the reference fails to provide a teaching, motivation, or suggestion that creates a reasonable expectation of success. At the end of the decision, the PTAB also took a concerning position regarding a obviousness-type double patenting rejection, holding that the filing of a terminal disclaimer in the prosecution of the commonly-assigned U.S. Patent over the Application on Appeal is an admission of the claims being an obvious variant. [Read more](#)

JPO UPDATES

[US-JP Collaborative Search Pilot Program Can Simplify Your Prosecution Process!](#)

BY KASUMI KANETAKA

US-JP Collaborative Search Pilot Program (herein "US-JP CSP") is a joint program between the USPTO and the JPO in which the examiners of both Offices examine the patent applications to share search results along with their opinions and provide the initial examination results from both Offices early to the applicants during the same time period.[1] [Read more](#)



AI & IP



Amgen and AI

BY SAMEER GOKHALE

On November 4, 2022, the U.S. Supreme Court granted *Amgen's* petition for *certiorari* regarding the Federal Circuit's enablement review in *Amgen Inc. v. Sanofi, Aventisub LLC, 987 F.3d 1080 (Fed. Cir. 2021)*. While the underlying case relates to Amgen's invalidated antibody patents, the Court's review will impact Artificial Intelligence (AI) patents since there is an ongoing challenge in obtaining broad AI claims that safely meet the requirements of 35 U.S.C. §112(a). For example, where a trained AI model is performing object recognition, the Court will likely clarify if the enablement standard requires (i) that the specification discloses to those skilled in the art how to "make and use" the claimed invention so that the AI model can be trained to detect a broad range of objects, or (ii) the specification will have to cumulatively identify and make all or nearly all possible recognition scenarios without substantial "time and effort"? For these reasons, patent practitioners in all technological fields, and especially AI inventions, should pay close attention to the ruling (and the language) that comes down from the Court when this case is decided. [Read more](#)

FEDERAL CIRCUIT UPDATES

Federal Circuit - Notices

BY DON MCPHAIL

(A) On November 15, 2022, Revised Protocols for In-Person Arguments were issued. Significantly, there is no longer a requirement to wear a mask while on court premises. There is also no longer a prohibition against recent international travel.

(B) On November 17, 2022, notice was provided that the Court was deferring adoption of the recently-proposed amendments to the Federal Circuit Rules of Practice in light of the public comments received. No new date was provided for incorporation of those amendments.

[Read more](#)



In re Apple, No. 2022-162 (Nov. 8, 2022) (Dyk, Reyna, Taranto)

BY DON MCPHAIL

After being sued for infringement in the Western District of Texas, Waco Division, Apple had moved the district court to transfer the case to the Northern District of California and had submitted a declaration from an Apple employee in support. Shortly before the close of venue discovery, Apple sought leave to supplement its motion with additional declarations from employees whom its original

Treehouse Avatar LLC v. Valve Corporation, No. 22-1171 (Nov. 30, 2022) (Loutir, Reyna, Stoll)

BY DON MCPHAIL

Treehouse Avatar had sued Valve for infringement of a patent directed to a method of collecting data from an information network. In an opinion by Judge Reyna, the panel affirmed the district court's decision that "the grant of a motion to strike expert testimony is not improper when such testimony is based on a claim construction that is materially different from the

declarant had consulted so as to bolster the credibility of his statements... [Read more](#)

construction adopted by the parties and the court.” [Read more](#)

ITC



[Use of ITC in Life Sciences](#)

BY RICHARD D. KELLY

The International Trade Commission remains an active venue for medical devices and other life science patents under 19 U.S.C. § 1337 (“337”). While the ITC is not attractive for ANDA cases where patentees often want to take benefit the 30 month stay of generic approval which is not available in ITC actions, its relatively quick procedures, approximately 16 months from

institution to final decision make it attractive to cases where 35 USC 271(e)(2) are not available... [Read more](#)

LIFE SCIENCES NEWS

[CareDx Request for Rehearing / Rehearing En Banc Denied](#)

BY RICHARD D. KELLY

On December 2nd the Federal Circuit denied CareDx Inc.’s request for rehearing of a panel’s decision affirming the decision of the Delaware District court that its test for transplant rejections was not patent eligible. CareDX was discussed in a July life Science Blog [here](#). Briefly the patent was directed to detecting an organ donor’s cell-free DNA, cfDNA, as an indication of organ rejection an admittedly known relationship... [Read more](#)



[U.S.Trade Representative Supports Delay of Vote on Expanded COVID-19 Related Carveout](#)

BY RICHARD D. KELLY

On December 6 the U.S. Trade Representative announced its support for a delay on the vote to expand to Covid-19 waiver of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights, or TRIPS. The current waiver applies to vaccines only while the proposed expansion includes diagnostics and therapeutics. The Trade Representative wants the U.S. International Trade commission to commence a probe relating to the diagnostics and therapeutics. The current waiver covering vaccine patents under the TRIPS agreement for five years, allowing member countries to access COVID-19 patents for vaccine production and making it so the U.S. cannot enforce certain IP rights on behalf of American companies... [Read more](#)



[Dangers May Lurk in an Acquired IP Portfolio](#)

BY RICHARD D. KELLY

In life sciences the purchase of products and related IP rights is common as is the acquisition of companies for their IP. Do a thorough due diligence on the IP to ascertain if all rights can be effectively transferred. This requires considering not only express licenses, but also implied licenses created because of prior licensing of related applications. In a recent Delaware case, *Horizon Medicines, LL. v. Apotex Inc.*, Civ 22-640-CB, Horizon discovered that it had not acquired all the IP rights to the product PENNSAID® it had purchased from Nuvo Research Inc. The issue was could a licensor grant a license to a future patent when that patent did not issue to the licensor. [Read more](#)

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