

JUNE 19, 2023

USPTO UPDATES

Additional Delay to the Effective Date of the **USPTO's Non-DOCX Filing Fee**

BY DAVID M. LONGO

The U.S. Patent and Trademark Office (USPTO) has once again delayed the implementation of the \$400 non-DOCX filing surcharge fee. The delay extends the effective date of the fee from June 30, 2023, to January 17, 2024. The USPTO will utilize this additional time to solicit public comments on the fee's impact and complete the necessary paperwork clearance process. Details are provided in the Federal Register published on June 6, 2023, and available here.

In addition, the USPTO has extended until further notice the option for submitting an applicantgenerated back-up PDF version of an application in addition to a validated DOCX version only when filing an application in Patent Center. Details are provided in another section of the Federal Register to be published on June 6, 2023, and available here.

Show Me the Money - USPTO Fee Proposals Include Fee Provisions to Impact Applicant Behavior BY RICHARD D. KELLY

The USPTO has opened the discussion on its fees to be effective in 2025. While the PTO is to be applauded for getting ahead of the fee curve, some proposed fees are not only significantly excessive but beyond the PTO's fee setting authority. The PTO's executive summary quoted in this post is found here along with other supporting documentation. Read our full blog post discussing the USPTO fee proposals here.

USPTO Announces Final Rule on Standardization of Patent Term **Adjustment Statement for Information Disclosure Statements** BY KURT M. BERGER

On June 15, 2023, the U.S. Patent and Trademark Office (USPTO) issued a final rule on the filing of a Patent Term Adjustment (PTA) statement regarding an Information Disclosure Statement (IDS). In particular, the USPTO is now requiring the use of its Form PTO/SB/133 along with an appropriate document code, with the goal of streamlining the process by more accurately capturing and accounting for the PTA statement "without unnecessary back-and-forth between the Office and applicant." According to the USPTO, failure to submit a PTA statement

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regarding IDSs without using the new form or the appropriate document code will require an applicant to request reconsideration of the PTA for the IDS to not be considered a failure to engage in reasonable efforts to conclude the prosecution of the application. There is no USPTO fee for filing the PTA statement using the required form PTO/SB/133.

The final rule specifically revises 37 C.F.R. § 1.704(d) to include a new paragraph (d)(3) requiring applicants to submit the statement required for the "safe harbor" on USPTO form PTO/SB/133 using the appropriate document code "PTA.IDS". When filed in this manner, the USPTO computer program that computes PTA will be able to automatically determine when the required "safe harbor" statement was filed.

Read our full post with more details here.

JPO UPDATES



Legal Protection from Generative AI in Japan (continued)

BY KASUMI KANETAKA

In **our blog post dated May 11, 2023**, we discussed the Japanese government's legal protections from generative artificial intelligence (AI) tools. Recently, on June 9, 2023, the Japanese government held a meeting for the Intellectual Property Strategic Program and discussed the generative AI as a major topic for the first time. The meeting

addressed the increasing risk of copyright violations, as AI technology allows the creation of text or images closely resembling original works. The government plans to develop a clearer definition of what constitutes copyright infringement as well as measures to protect the rights of creators. At the same time, the government seeks to consider how the technology can be best developed with generative AI, as utilizing generative AI can improve efficiency in creative fields. Read our full blog post here.

Dwango v. FC2: Japanese Patent Enforceability When a Part of the Infringement Takes Place Outside Japan

BY KASUMI KANETAKA

On May 26, 2023, Japan's Intellectual Property High Court (IPHC) has ruled that FC2, a USbased internet firm, has violated a patent owned by Dwango, which operates video-sharing website Niconico, overturning a lower court decision, according to the NHK WORLD-JAPAN. The IPHC was established in 2005 as a special branch within the Tokyo High Court. Dwango sued FC2, accusing the US-based company of infringing its patent on a function to automatically scroll users' comments on the screen of live-streamed videos. The Tokyo District Court ruled that FC2 was not violating the Dwango's patent because FC2's servers are located in the United States which would not violate the territorial principle of the Japanese patent law. Dwango appealed at the IPHC.

Presiding Judge Otaka Ichiro stated that even if servers are located outside Japan, companies will be subject to the patent law when the roles of system components in Japan and other factors are considered. Judge Otaka concluded that FC2's services are subject to Japanese patent law and ordered FC2 to stop distributing videos and pay about 80,000 dollars in damages.

The lawsuit was the first in which public opinions were solicited over issues of contention. According to the Tokyo High Court, among 52 opinions received from companies and individuals, 44 were submitted as evidence.

FEDERAL CIRCUIT UPDATES

CAFC Addresses Requirements for Award of Attorneys' Fees

BY DONALD R. McPHAIL

In a pair of precedential opinions last month, two different panels of the Federal Circuit addressed the requirements for an award of attorneys' fees.



The first was issued in United Cannabis Corporation v. Pure Hemp Collective Inc., No. 2022-1363 (May 8, 2023), which involved an appeal of a denial of a motion for attorneys' fees, and the district court's inherent authority. United Cannabis had filed suit against Pure Hemp for patent infringement in 2018, asserting U.S. Patent No. 9,730,911. UCANN's infringement claim was dismissed with prejudice, and Pure Hemp's invalidity and inequitable conduct claims were dismissed without prejudice. In April 2021, Pure Hemp moved for an award of attorneys' fees. The district court denied Pure Hemp's motion, finding that Pure Hemp had failed to establish that Pure Hemp was a "prevailing party" under section 285, that the case was exceptional, or that UCANN's counsel had acted in a vexatious or otherwise unreasonable manner. Pure Hemp then appealed. The Federal Circuit affirmed the district court's denial of Pure Hemp's motion for attorneys' fees. The panel held that the district court had, in fact, erred by not finding that Pure Hemp was the prevailing party in the underlying action. The panel further held, however, that, despite this error, the district court had correctly denied Pure Hemp's motion because it had concluded that Pure Hemp had failed to establish that the case was exceptional-an essential element of Pure Hemp's motion. Turning to the issue of the alleged inequitable conduct, the panel noted that it had no findings on either materiality or intent to deceive that it could review because the district court had made no findings. The panel also rejected Pure Hemp's argument that the case should be found exceptional because UCANN's attorneys had a conflict of interest in prosecuting identical applications for two different clients. First, the panel found that Pure Hemp had waived this argument by failing to cite the applicable rule of professional conduct to the district court. Secondly, the panel held that Pure Hemp's challenge lacked merit.

The second opinion was issued in OneSubsea UK Limited v. FMC Technologies, Inc., No. 2022-1099 (May 23, 2023). OSS had originally brought suit against FMC in the United States District Court for the Eastern District of Texas in March of 2015, asserting ninety-five claims spread across ten patents. FMC countersued, alleging infringement of twenty-nine claims from two patents, and sought transfer to the Southern District of Texas where both parties maintained their respective headquarters. The case was transferred over OSS's objections. In January 2021, FMC filed a motion for attorneys' fees, arguing that OSS's "substantively weak infringement claims" and "litigation misconduct" satisfied the test for an "exceptional" case. In particular, FMC argued that the court's Markman order had foreclosed any legitimate argument that FMC's apparatus infringed the asserted claims and that OSS had engaged in litigation misconduct by. inter alia, offering the opinions of an expert who disregarded claim constructions and by filing the original complaint in the Eastern District of Texas. In September 2021, the district court denied FMC's motion for fees, and FMC appealed. The CAFC rejected FMC's argument that the case was objectively baseless after the district court issued its Markman order construing certain disputed claim terms. The panel noted that the district court itself had stated that it was "unclear" whether FMC would ultimately prevail on that issue when deciding to stay the case and had specifically pointed out at the time that OSS had offered the opinions of an expert that raised a disputed issue of fact. The panel also rejected FMC's argument that OSS's failure to produce admissible evidence to support its infringement theory alone made the case exceptional, noting specifically that FMC had cited no case that found a case exceptional solely because a party relied on evidence that was ultimately found to be inadmissible. Read our full blog post for the two opinions here.

PTAB Reversed - Petitioner Failed to Argue Prior Art was Analogous to Claim

BY RICHARD D. KELLY

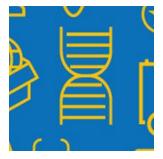
The Federal Circuit in *Sanofi-Aventis Deutschland GMBH v. Mylan Pharms Inc.*, Appeal No. 2021-1981, reversed the PTAB decision that the Sanofi-Aventis injector pen Patent RE47,614 was obvious over U.S. Patent 4,144,957 (de Gennes) when combined with two other references (Burren and Venezia). Mylan relied on Burren as the primary reference which it asserted was analogous to '614 but never argued that the de Gennes was analogous to the '614 claimed invention. The PTAB found that the combination of only Burren with Venezia did not render the '614 claims obvious but did find the combination of Burren with Venezia and de Gennes did render the '614 claims obvious. The PTAB found de Gennes to be analogous to the injector pen art even though de Gennes related to automobile clutches. The PTAB considered de Gennes to be highly relevant because it solved a problem in the Burren reference.

The Federal Circuit disagreed because Mylan had presented no evidence establishing that de Gennes met either of the two parts of the analogous art test which are: (1) the prior art is in the same field of endeavor as the inventor regardless of the problem addressed, and (2) if not within the same field, whether the reference is reasonably pertinent to the problem addressed by the inventor. Here, Mylan presented evidence that de Gennes was related to the problem with Burren, but no evidence regarding its relevance to the claimed invention. Mylan argued that by presenting evidence of a relationship between de Gennes and Burren it had met its burden.

The Federal Circuit citing *In re Clay*, 966 F.2d 656, 658–59 (Fed. Cir. 1992) held that the purpose of the prior art stated "must be evaluated *with reference to* the inventor's purported invention disclosed within the challenged patent." *Id.* ("If a reference disclosure has the same purpose *as the claimed invention*, the reference relates to the same problem, and that fact supports use of that reference in an obviousness rejection.") Since Mylan had not related the de Gennes disclosure of automobile clutches to medical injector pens, the panel reversed the PTAB's decision.

This is a reminder that it is essential to relate the prior art to the claimed invention where it is from an unrelated field.

LIFE SCIENCES UPDATES



Amgen v. Sanofi - History Repeated BY RICHARD D. KELLY

The Supreme Court Affirmed the Federal Circuit's decision in *Amgen* v *Sanofi* in mid-May. Our blog post on the decision is found **here**. The Supreme Court did not adopt the law of the Federal Circuit law on enablement but, instead, relied on its case law from the 19th and early 20th century. In doing so, the Court drove a nail through the heart of claiming antibodies with functional language with its

discussion of *Holland Furniture Co.* v. *Perkins Glue Co.*, 277 U.S. 245 (1928). In *Holland*, the claims were drawn to a furniture glue described by its function rather than its composition. The *Holland* Court at 256 described the composition as one where the "starch ingredient was to possess such qualities that when combined with three parts of water and with alkali it would produce a product "as good as animal glue" for veneering, or having the properties of animal glue, these properties being described in terms of its functions." The Court went on state:

But an inventor may not describe a particular starch glue which will perform the function of animal glue and then claim all starch glues which have those functions, or even all starch glues made with three parts of water and alkali, since starch glues may be made with three parts of water and alkali that do not have those properties. See *The Incandescent Lamp Patent*, 159 U.S. 465, 472.

The Court analogized what Amgen was seeking to claim "sovereignty over [an] entire kingdom" of antibodies. The Court saw this as no different than *Incandescent Lamp* which sought to claim all fibrous and textile materials for light bulbs or *Holland* which sought to claim all starch glues that worked as well as animal glue. The Court cited its precedent where a reasonable amount of experimentation to make and use an invention did not doom patent claims for lack of enablement. The Court stated what was reasonable will depend on the invention and the state of the underlying art described by Amgen's expert as "[T]he way in which you get from sequence to that three-dimensional structure isn't fully understood today. It's going to get a Nobel Prize for somebody at some point, but translating that sequence into a known three-dimensional structure is still not possible." The three-dimensional structure is at least as important as the antibody's amino acid sequence. Amgen provided the needed information for only 26 antibodies but sought a monopoly over all that (1) bind to specific amino acids on a naturally occurring protein known as PCSK9, and (2) block PCSK9 from impairing the body's mechanism for removing LDL cholesterol from the bloodstream.

Amgen's argument that an affirmance risked "destroy[ing] incentives for breakthrough inventions" was dismissed by the Court noting that this was a policy judgment belonging to Congress. The Court noted that the enablement mandate had been in the patent statute since 1790 and the Court's duty was to apply it faithfully. The Court concluded with:

Section 112 of the Patent Act reflects Congress's judgment that if an inventor claims a lot, but enables only a little, the public does not receive its benefit of the bargain. For more than 150 years, this Court has enforced the statutory enablement requirement according to its terms. If the Court had not done so in *Incandescent Lamp*, it might have been writing decisions like *Holland Furniture* in the dark. Today's case may involve a new technology, but the legal principle is the same.

As Sir Edmund Burke said: "Those who don't know history are doomed to repeat it." That happened in *Amgen*.

CareDx Petition for Certiorari - An Update

BY RICHARD D. KELLY

Simultaneous with our May 30 blog post on the CareDx petition, **here**, the Supreme Court requested Eurofins and Natera to respond by June 29 to the amicus brief filed by retired Chief Judge Paul Michel and Professor John Duff supporting the CareDx certiorari petition. Both Eurofins and Natera had filed waivers of the right to respond to the CareDx petition.

The recent Supreme Court decision in *Amgen v. Sanofi* underscores the correctness of CareDx in its petition to focus on the claims and the fact that the claims do not monopolize noninvasive tests for organ rejection. In *Amgen* the Supreme Court described Amgen's patents as purporting "to claim for itself 'the entire genus' of antibodies that (1) 'bind to specific amino acid residues on PCSK9,' and (2) 'block PCSK9 from binding to [LDL receptors]." *Amgen*, 872 F. 3d, at 1372. Still further the Court characterizes "Amgen seeks to *monopolize* an entire class of things defined by their function—every antibody that both binds to particular areas of the sweet spot of PCSK9 and blocks PCSK9 from binding to LDL receptors." [Emphasis added]. One hallmark of the Court's prior patent eligibility decisions, as noted by the CareDx petition, is the monopolization of the judicial exceptions by the claims.

CareDx has wisely stressed the scope of its patent claims to show the lack of monopolization, and its specification acknowledges two prior art methods for performing the same task albeit not as well as its patented technique. The Court's reference to monopolization of technology gives us hope that the Court will grant certiorari in CareDx and put the Federal Circuit on the right track on the question of patent eligibility.

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