OBLON

IPUPDATES

FEBRUARY 19, 2024

USPTO UPDATE

Assignment Center Fully Replaces EPAS and ETAS

BY GRACE E. KIM

On February 5, 2024, the new assignment system, Assignment Center, fully replaced the Electronic Patent Assignment System (EPAS) and Electronic Trademark Assignment System (ETAS) for processing all patent and trademark assignment requests. The Assignment Center is intended to be a user-friendly system that guides customers through each step of the assignment process and provides a central location to track the submitted application's status. Note that the location to **search for patent and trademark assignments** did not change.

The USPTO has provided how-to guides on using Assignment Center for **patents** and **trademarks** and **training videos** to help transition to the new system.

JPO UPDATES

Global Intellectual Property Strategy Forum 2024

BY KASUMI KANETAKA

On January 25, 2024, the Japan Patent Office (JPO) and the National Center for Industrial Property Information and Training (**INPIT**) hosted the Global Intellectual Property Strategy Forum 2024. Please see **here** for the forum report from 2023.

One of the topics discussed during the forum was an application of Green Transformation Technologies Inventory (GXTI) for evaluating technologies related to Green Transformation (GX). The GXTI, published by the JPO in 2022, can be used for analyzing and searching patent documents. One feature of the GXTI is that it gives a bird's eye-view of GX technology from five GX Technologies (gxA-gxE) and four perspectives for cross tabulation (gxY) (see **GXTI**). Another feature is that the GXTI contains patent search formulas which consist of International Patent Classifications (IPCs).

The JPO promotes that the IPC search formulae make it possible for anyone to conduct a global patent information analysis under the same conditions (see **here**). Since the analysis can be

conducted under the same conditions, third parties can also compare an evaluate the same search results and analysis.

Please see **here** for more information about the GXTI.

JPO Published Guidebook for Overseas Users on Design System in Japan

BY KASUMI KANETAKA

The JPO published "**Your Key to Success: for Obtaining a Design Right in Japan**." This is a guidebook in English for overseas users to provide information on the design system in Japan.

Please see **here** for more information.

Japan AI Safety Institute Launched

BY KASUMI KANETAKA

The Japanese government launched Japan AI Safety Institute (AISI) on February 14, 2024, within the Information-technology Promotion Agency (IPA). This national research institute will examine the evaluation methods for AI safety and other related matters. Please see **here** for more information.

AI UPDATES

USPTO Clarifies Guidance to Judicial Boards on Holding Parties Responsible for the Misuse of AI in Legal Proceedings

BY SAMEER GOKHALE

On February 6, 2024, USPTO Director Kathy Vidal issued guidance clarifying the existing rules regarding using Artificial Intelligence (AI) in the drafting of submissions to the Patent Trial and Appeal Board (PTAB) and Trademark Trial and Appeal Board (TTAB). Notably, the guidance addresses the concerns that AI will be misused or left unchecked and states "any paper submitted to the USPTO under signature must be reviewed by the person presenting the paper…Simply assuming the accuracy of an AI tool is not a reasonable inquiry." The guidance also describes sanctions for submissions which include misstatements of facts or law. A copy of the Director's memorandum can be found **here**.

USPTO Issues Inventorship Guidance and Examples for AI-Assisted Invention

BY SAMEER GOKHALE

On February 13, 2024, the United States Patent and Trademark Office issued inventorship guidance for inventions assisted by artificial intelligence (AI). The guidance is made pursuant to the "Executive Order on the Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence" from October 30, 2023. The guidance provides clarity for USPTO stakeholders and personnel on how the USPTO will analyze inventorship issues for AI systems. The guidance explains that the inventorship analysis should focus on human contributions and that AI-assisted

inventions are not categorically unpatentable. The guidance provides procedures for determining whether a natural person provided a significant contribution to the invention. The guidance discusses the impact these procedures have on other aspects of patent practice. The USPTO is seeking public comments on the guidance by May 13, 2024. The Notice for the guidance can be found **here**.

LIFE SCIENCES NEWS

Cellect's Petition for Rehearing *En Banc* Denied

BY RICHARD D. KELLY

Cellect LLC.'s petition for rehearing *en banc* was denied on January 19, 2004, of its decision in *In re Cellect, LLC*, 81 F.4th 1216 (Fed. Cir. 2023), where it found that for a double patenting determination the PTA is included in the time for an obviousness type double patenting (ODP) determination. This contrasts with where the patent received PTE where double patenting is determined before the addition of the PTE. The decision has implications for pharma patents where PTA is common and patentees often file continuing application to maintain claim pendency. Given the importance of patents to pharma companies to earning a return on their investment in R&D, companies should review their portfolios for potential issues which could adversely affect the life of patent protection for their drugs. Proactive abandonment of the later filed but earlier expiring patent may be possible to avoid an invalidity finding on ODP while maximizing patent life.

Securing Diagnostic Technique and Biomarker Patents

BY RICHARD D. KELLY

Since the Supreme Court decision in *Mayo*, diagnostic and biomarker patents have not had a good success rate in litigation. The Federal Circuit's decision in *Sequenom* was bemoaned by many commentators. The comments of IP Watchdog and Judge Linn in his dissent were typical, referencing "the invention" not the claims to which the decision was directed. IP Watchdog in a June 27, 2016 post described the Court's decision as having "ruled a truly revolutionary medical test to be patent ineligible." The commentators ignored that the Court had not ruled the invention to be patent ineligible, but the claims. The commentators overlooked the Court's observation that although Sequenom had asserted all claims rose or fell together, several claims differed from the representative claim, but it was bound by Sequenom's representation. A comparison of representative claim 1 and claim 24, noted by the Court to be different, reveals the difference:

> Claim 1. A method for detecting a paternally inherited nucleic acid of fetal origin performed on a maternal serum or plasma sample from a pregnant female, which method comprises:
>
> amplifying a paternally inherited nucleic acid from the serum or plasma sample and detecting the presence of paternally inherited nucleic acid of fetal origin in the sample
>
> Claim 24. A method for detecting a paternally inherited nucleic acid on a maternal blood sample, which method comprises:
>
> **removing all or substantially all nucleated and anucleated cell populations from the blood sample,**
>
> amplifying a paternally inherited nucleic acid **from the remaining fluid** and
>
> detecting the presence of paternally inherited nucleic acid of fetal origin in the sample

Claim 24 contains an additional step not found in the “representative” claim. In the summary of the invention in U.S.P. 6,258,540, the inventors described their invention as follows:

> It has now been discovered that foetal DNA is detectable in maternal serum or plasma samples. This is a surprising and unexpected finding; maternal plasma is the material that is routinely discarded by investigators studying noninvasive prenatal diagnosis using foetal cells in maternal blood.

What the commentators failed to recognize was that the invention was not in the representative claim. The representative claim was claiming the failed prior art technique. The controversy surrounding the decision could have been avoided if the Court had pointed out the representative claim omitted the invention. It is also a lesson for everyone trying to understand the Court’s decisions regarding “judicial exceptions.” A decision which seems to make no sense becomes understandable when it is viewed with the patent description.

The problem encountered in understanding the *Sequenom* decision is seen again in *Athena Diagnostics, Inc. v. Mayo Collaborative Servs. LLC,* 915 F.3d 743 (Fed Cir. 2019), petition for reh’g *en banc denied*, 927 F.3d 1333 (Fed. Cir. 2019) where the diagnostic claims in U.S.P. 7,267,820 were found to be patent ineligible as directed to a natural law. The patent was directed to diagnosing a neurological condition, *Myasthenia gravis* ("MG"), by detecting antibodies to the protein muscle-specific tyrosine kinase ("MuSK"). The claims were:

> Claim 1. A method for diagnosing neurotransmission or developmental disorders related to muscle-specific tyrosine kinase (MuSK) in a mammal comprising the step of detecting in a bodily fluid of said mammal autoantibodies to an epitope of muscle-specific tyrosine kinase.
>
> Claim 7. A method according to claim 1, comprising
>
> contacting MuSK or an epitope or antigenic determinant thereof having a suitable label thereon, with said bodily fluid,
>
> immunoprecipitating any antibody/MuSK complex or antibody/MuSK epitope or antigenic determinant complex from said bodily fluid and
>
> monitoring for said label on any of said antibody/MuSK complex or antibody/MuSK epitope or antigen determinant complex,
>
> wherein the presence of said label is indicative of said mammal is suffering from said neurotransmission or developmental disorder related to tyrosine kinase (MuSK).

The relationship between MG and MuSK is a natural law as is the binding between the antibody and MuSK. Before this invention, the conventional test for MG involved testing for antibodies against acetyl choline receptor (AChR). This test was only 80% accurate, returning a false negative in about 20% of the patients with MG which could delay their treatment which improved both the length and quality of life for patients with the disease. The problem is that the claims preempt the natural law and do not reflect what the inventor described as his invention in the specification. The inventors describe their invention as detecting the presence of MG in the 20% of patients who are MG negative in the conventional test but have the disease, “subclass or subtype of MG, which is generally found in patients who do not exhibit the ability to immunprecipitate radio labelled AChR with their bodily fluids.” (Col. 3, lines 1 – 3). “Thus advantageously, an assay system for detecting neurotransmission disorders, and particularly *Myasthenia gravis* in patients who are anti-AChR autoantibody negative (AAAN) is provided. Prior to the present invention there was no basis for providing an immediate clinical diagnosis for such patients.” (Col. 4, lines 17 – 22). The claims were not focused on the invention but rather on the natural law which potentially provided the greatest protection but for being drawn to a patent ineligible natural law.

The challenge in judicial exception cases for both patent drafters and litigators is to be disciplined and focus on the invention when drafting claims or selecting representative claims.

Only One IPR per Patent

BY RICHARD D. KELLY

On February 5, 2024, the PTAB decided that IPR2023-01252 brought by DexCom against Abbott Diabetes Care patent 11,298,056 was not "the rare case" where filing more than one IPR petition against a patent by the same petitioner was warranted in denying institution of the IPR. The '056 patent is directed to continuous glucose monitors (CGM) where a gap in the results occurs because of a need to calibrate the sensor. DexCom filed two IPRs against '056, assuming an application filing date of April 30, 2019, for '056, IPR2023-01252 (Ranked by DexCom as Petition 2), and the other an effective filing date of 2009, IPR2023-01251 (Ranked as Petition 1).

DexCom argued for two IPRs based on the priority dispute, citing the Trial Practice Guide for the concept that more than one petition may be necessary when there is a dispute about priority date requiring arguments under different references. DexCom ignores the wording "may be needed, although this should be rare." See Trial Practice Guide at 59. What DexCom's ranking did was obviate any need for the PTAB to determine whether '056 was entitled a 2009 filing date or a 2021 filing date, since that issue was not put into dispute in Petition 1, and if petition 1 was granted the PTAB need not decide petition 2. Abbott's Patent Owner Statement obviously didn't challenge its benefit of the 2009 filing date. Thus, the filing date issue fell out because of DexCom's strategy.

The PTAB was unimpressed with DexCom's other argument -- the length and number of claims is another reason for multiple claims. Abbott and PTAB noted there was only one independent claim and DexCom had failed to demonstrate that either the number of claims or their length was unusual. One can speculate that the result might have been different had the petitions been ranked differently. Had petition 2 been ranked first, then the PTAB would have to decide the '056 effective filing date. If it determined the patent was entitled to the 2009 filing date, then it would be necessary to consider petition 1. Here since petition 1 did not challenge the filing date, there was no reason to consider the second petition since the filing date was not at issue.

In considering whether to file more than one petition, one should carefully consider whether is it necessary, and if so, the ranking of the petitions. Here once the PTAB granted Petition 1, Petition 2 became moot.

NEWSLETTER EDITOR: **SAMEER GOKHALE**