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IP UPDATES

DECEMBER 30, 2024

USPTO UPDATE

USPTO Announces Fee Increases Effective January 19, 2025

BY PHILIPPE J.C. SIGNORE, PHD

The United States Patent and Trademark Office (USPTO) has finalized fee increases set to take effect on January 19, 2025. Certain fees will rise significantly. Below is an overview of some of the most notable changes. The “undiscounted” fees discussed below apply to large entities, but discounts are available for small and micro entities. Further details are available on the **USPTO’s website**.

The upcoming fee adjustments by the USPTO introduce several key changes to patent-related costs based on the following framework: An approximate 7.5% increase will apply “across the board” to all patent fees that are not “targeted." Examples of non-targeted fees include the fees for filing a terminal disclaimer and maintenance fees. Additionally, "front-end" patent fees, which include filing, search, and examination fees, will experience an additional 2.5% increase resulting in a total front-end increase of 10%. For our complete summary of the announcement, please click **here**.

USPTO Withdraws Proposed Changes to Terminal Disclaimer Practice

BY DAVID M. LONGO, PHD

The U.S. Patent and Trademark Office (USPTO) announced on December 4, 2024, that it is withdrawing the Notice of Proposed Rulemaking published in the Federal Register on May 10, 2024. According to the USPTO, "In light of resource constraints, the USPTO has decided not to move forward with the proposed rule at this time and to withdraw the proposed rule. Despite the decision not to move forward with the proposed rule at this time, the USPTO appreciates and takes seriously the thoughtful perspectives raised by commenters." For our complete summary of the announcement, please click **here**.

CAFC UPDATE

Ericsson v. Lenovo Signals Potential Impact for Litigation Involving Standard Essential Patents (SEPs)

BY SAMEER GOKHALE

On October 24, 2024, the Federal Circuit issued a precedential opinion in the case of *Telefonaktiebolaget LM Ericsson v. Lenovo (United States), Inc.*, No. 24-1515 (Fed. Cir. Oct. 24, 2024). Lenovo and Ericsson had been trying to agree on a global cross-license to SEPs of the other, which would include Ericsson's 5G SEPs. The Federal Circuit sided with Lenovo on this matter, and vacated the district court's denial of Lenovo's antisuit-injunction request, by finding that Ericsson's FRAND commitment precludes it from seeking SEP-based injunctive relief unless it has first negotiated in good faith over a license to those SEPs. Click **here** for the full opinion.

JAPAN IP UPDATE

JPO Publishes Report on Recent Trends in AI-related Inventions

BY SAMEER GOKHALE

In December, the Japan Patent Office (JPO) issued a detailed report on recent trends in AI-related inventions. The JPO provided the following summary from the report.

- The number of domestic applications for AI-related Inventions has been increasing since 2014, with approximately 10,300 applications filed in 2022. The number of applications for which G06N (AI Core Technology) as FI has been allocated was approximately 3,000 in 2022, and is still on the rise, although the growth has slowed slightly.

- In recent years, among deep learning techniques, especially generative AI such as ChatGPT has been the subject of evaluation in various tasks in academia, as well as a subject of social discussion, and its impact on future AI-related inventions is expected.

- As the main classification of AI-related Inventions, G06T, G06V (Image Processing/Recognition) is the most common, other than G06N (AI Core Technology). The number of technical fields that can be grouped under "Others" is also on the rise, suggesting that the application of AI technology is expanding.

- The number of applications for AI-related Inventions referring to CNN has been increasing since 2014. On the other hand, the number of applications for AI-related Inventions referring to deep reinforcement learning has remained flat in recent years. In addition, the number of applications for AI-related Inventions referring to transformers has been on the rise, surpassing that of deep reinforcement learning in 2020.

- It can be seen that the number of applications allocated with G06N (AI Core Technology) granted is on the rise in Japan, Europe, China and Korea. In particular, China is outstanding. Therefore, it can be said that China is the major application destinations among five IP offices.

For the full report, click **here**.

LIFE SCIENCES NEWS

The Strange Journey of a PGR Request

BY RICHARD KELLY

Neuroccrine Biosciences (Petitioner) filed a PGR request for U.S.P. 10,849,908 on May 21, 2021, as PGR2021-00088. Claim 1 of '908 is representative of the challenged claims:

> 1. A method of treating congenital adrenal hyperplasia (CAH) in a human comprising administering to the human a therapeutically-effective amount of a CRF 1 receptor antagonist or a pharmaceutically acceptable salt thereof, wherein an adrenocorticotropic hormone (ACTH) level in the human is reduced by at least 10% from baseline.

The specification identified a single compound having the claimed functions. Note that there is not a single structural limitation in the clam. It is attempting to preempt an entire field. Petitioner requested review based on inherent obviousness and written description. The PTAB denied the Petition finding the evidence that the prior art inherently anticipated the prior art to be insufficient since the prior art used a different compound from that of the publication to show that the prior art inherently met the claims. However, the claims do not specify any structure, only function. The PTAB denied the inherent obviousness because "Petitioner has not demonstrated that all, or even a representative number of this genus have necessarily demonstrated an 'at least 10% reduction in a patient's ACTH level from baseline'" ignoring that the '908 patent disclosed only a single species and no common structural features.

The PTAB denied the written description request which was based on the failure of the '908 patent to disclose either a representative number of species or common structural features, citing *Ariad Pharm., Inc. v. Eli Lilly & Co.,* 598 F.3d 1336 (Fed. Cir. 2010) (en banc). While the prior art did show CRF1 receptor antagonists broadly there was no discussion in '908 of what structure was necessary to achieve an adrenocorticotropic hormone (ACTH) level in the human is reduced by at least 10% from baseline.

The PTAB ignored the red flags found in the provisional application, the abstract, and the specification where the invention was described as the use of -(4 -Chloro - 2- (morpholin -4 -yl) thiazol 5 -yl)-7-(1- ethylpropyl)-2,5 - dimethylpyrazolo (1,5 -a) pyrimidine to control adrenocorticotropic hormone (ACTH) level in humans (see below).

> The present invention provides novel pharmaceutical compositions comprising -4 -Chloro - 2-(morpholin -4 -yl) thiazol 5 -yl)-7-(1-ethylpropyl)-2,5 - dimethylpyrazolo (1,5 -a) pyrimidine and methods of using the same for the treatment of Congenital adrenal hyperplasia (CAH). (Abstract)
>
> The present invention provides novel pharmaceutical compositions comprising 3- (4 - Chloro -2-(morpholin - 4-yl) thiazol - 5 -yl) -7-(1-ethylpropyl) -2,5 -dimethylpyrazolo (1,5 - a) pyrimidine and methods using such pharmaceutical compositions for treating congenital adrenal hyperplasia (CAH) . (Col. 1, ll 30 – 33)
>
> The provisional application was limited to 3- (4 - Chloro -2- (morpholin - 4 - yl) thiazol - 5 - yl) -7-(1 -ethylpropyl) -2,5 -dimethylpyrazolo (1,5 - a) pyrimidine. The regular utility application simply added the generic concept which became the sole concept claimed.

It isn't until column 11 in the utility application that the claimed concept appears, but it is devoid of structural limitations relying on the single compound as an example. There is no discussion of the structural limitations to achieve the claimed result. Yet the PTAB denied the request because the class of compounds was known and that examples are not necessary. The PTAB denied the

Petition because Petitioner provided no evidence of undue experimentation even though patentee had argued that the activity of the single disclosed compound, **tildacerfont,** was unexpected. No evidence was provided that other different compounds would exhibit the effect. There was no explanation why, if the results were unexpected for tildacerfont, how one could expect other CRF 1 antagonist compound to exhibit the claimed property.

The PTAB applied a double standard, one to prove inherency and the other, lower standard for written description and ignored the red flags in the specification.

The Petitioner had also asserted inherency in prior art treating congenital adrenal hyperplasia (CAH) but not showing the baseline data. Petitioner relied on a non-prior art reference which demonstrated that one member disclosed in the prior art reference achieved the claim baseline result. The PTAB denied this request because it considered that the Petitioner was improperly relying on non-prior art ignoring that it was simply relying on the reference to show that a prior art reference inherently met the baseline limitation.

The Petitioner requested reconsideration and Precedential Opinion Panel ("POP") review. Katherine K. Vidal, Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office who on July 20, 2023, issued an order granting *sua sponte* Director Review (Paper 14) and the POP dismissed the request for POP review (Paper 15). Under Secretary Vidal's opinion relied upon the well-known concept that a species anticipated a genus claim. The PTAB had failed to grasp a basic patent law concept. Under Secretary Vidal also noted that the Petitioner was not relying on the non-prior art reference to show inherency but to show that the prior art reference inherently met the claimed baseline limitation, citing the Federal Circuit in citing *Hospira, Inc. v. Fresenius Kabi USA, LLC*, 946 F.3d 1322, 1329 (Fed. Cir. 2020)) has held that "[e]xtrinsic evidence can be used to demonstrate what is 'necessarily present' in a prior art embodiment even if the extrinsic evidence is not itself prior art." Hospira, 946 F.3d at 1329. The court explained that "[t]he later evidence is not itself prior art; it only helps to elucidate what the prior art consisted of." Id. at 1330.

With respect to the written description issue the petition was also granted with the Under Secretary Vidal quoting the Federal Circuit *Ariad Pharm., Inc. v. Eli Lilly & Co*., 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc) opinion quoting *Eli Lilly,* 119 F.3d at 1568–69: "[S]ufficient description of a genus . . . requires the disclosure of either a representative number of species falling within the scope of the genus or structural features common to the members of the genus so that one of skill in the art can 'visualize or recognize' the members of the genus." Vidal went on to quote from *AbbVie Deutschland GmbH & Co., KG v. Janssen Biotech, Inc.*, 759 F.3d 1285, 1301 (Fed. Cir. 2014) "Functionally defined genus claims can be inherently vulnerable to invalidity challenge for lack of written description support, especially in technology fields that are highly unpredictable, where it is difficult to establish a correlation between structure and function for the whole genus or to predict what would be covered by the functionally claimed genus." For reasons which are not clear, the PTAB had chosen not to follow the existing case law even though cited by the Petitioner in its petition. On remand, the PTAB (three and one-half years after the Petition had been filed) finally received a final written decision finding the '908 claims to lack adequate written description.

This case is concerning because the PTAB (which decides IPRs and PGRs) showed a lack of appreciation for the relevant case law and that a non-prior art reference can provide evidence that a prior art reference inherently anticipates the claims, and the length of the proceeding where the decision on petition took over one year and the following PTAB decision an additional one and one-half years.

This decision reminds practitioners when drafting applications to avoid the use of only functional language in claiming an invention. One needs to be alert when converting from a provisional to a regular utility that any subject matter added is adequately described. Here there were several warning flags that the added disclosure had inadequate description especially the inconsistency between the Abstract and the claims and in the specification itself.

For those pursuing IPRs or PGRs that petition for POP review, it may be useful where the PTAB can be shown to have not followed or ignored relevant case law.

NEWSLETTER EDITOR: **SAMEER GOKHALE**