OBLON

IPUPDATES

OCTOBER 16, 2023

USPTO UPDATES

USPTO Publishes Proposed Final Rule Regarding Internal Review Pre-Issuance of PTAB Decisions

BY RICHARD D. KELLY

On October 6 the USPTO published in the Federal Register a proposed rule to replace the May 27, 2022, interim process for reviewing PTAB decisions before issuance (Proposed rule **here**). The proposed rule is similar to the interim procedure which involves pre-issuance circulation of decisions for review by a group of non-supervisory APJs before issuance to obtain feedback about potential conflicts or inconsistencies with prior decisions or law. By formalizing the procedure, it becomes binding on the Office including the provision that the Director is not involved in a decision prior to issuance. The goal is to further make the PTAB decision process more transparent. The goal is to remove the suspicion that the USPTO management influences the PTAB decision making process leaving the only official route post issuance review by the Director.

Comments on the proposed rule must be filed by December 5, 2023.

JPO UPDATES

JPO's System Update in Examining AI-Related Inventions

BY KASUMI KANETAKA

On September 21, 2023, the Japan Patent Office (JPO) announced that they launched a Team Supporting AI Examinations, an internal body in which the respective examination divisions collaborate outside the technical fields they are responsible for in examinations of AI-related inventions. The JPO announced that it would enhance a system for the team to achieve efficient and highest-quality examinations of AI-related inventions.

As background, the JPO, in January 2021, inaugurated the team responsible for developing an examination environment for AI-related inventions. This idea was in response to developing AI-

related technologies, mainly deep-learning technologies, and the growth of the number of patent applications for inventions involving AI-related technologies in a variety of fields. As a part of enhancing the system in examining AI-related inventions, the JPO, starting on October 1, 2023, increased the number of experts on AI examination from around 10 to around 40. Previously, the JPO had assigned experts on AI examination only to the examination offices in charge of the fields where AI technology had been examined frequently. Now, it will designate one expert on AI examination to all examination offices, thereby enhancing the system for the team. It will provide experts on AI examination with opportunities to keep improving their knowledge of the latest AI technology, including the provision of training courses by external experts and other lecturers. Through this effort, the team can appropriately support examination of AI-related inventions even in fields where AI technology has not been frequently used.

Please see **here** and also **here** for more information.

KIPO UPDATES

Revisions to Accelerated Examination and Patent Term Adjustment

BY GRACE E. KIM

Effective January 1, 2024, the Korean Intellectual Property Office (KIPO) announced a bill including proposed revisions to accelerated examination and patent term adjustment. According to the revisions, accelerated examination will no longer be able to be requested based on the option of submitting the results of a prior art search. However, foreign applicants may still request accelerated examination under the Patent Prosecution Highway (PPH) Program. Regarding patent term adjustment, KIPO has included two additional delays as being attributable to the application, which affect the following periods of time: (i) receipt of Notice of Allowance, filing of a request for continued examination, until issuance of new Notice of Allowance, and (ii) receipt of final rejection until filing a Notice of Appeal. The proposed revisions are currently under public comments and legislative review.

FEDERAL CIRCUIT UPDATES

Federal Circuit Clarifies Functional Claim Test

BY RICHARD D. KELLY

The Federal Circuit on October 6, in IPR 2020-01099, used its review of the PTAB's final written decision to clarify functional claiming. Claim 5 was at issue:

> 5. A radio system comprising:
> a transmitter and a receiver having a radio connection to the transmitter;
> the transmitter comprising a channel coder for channel coding a data block into a coded data block by using a selected channel coding and for puncturing the coded data block by using a first puncturing pattern, and transmission means for transmitting the coded data block punctured by the first puncturing pattern to the receiver; and
> the receiver comprising a channel decoder for de- coding the received coded data block, *means for detecting a need for retransmission of the received coded data block*, and

> means for transmitting a retransmission request of the coded data block to the transmitter; wherein:
> the channel coder increases the code rate of the coded data block to be retransmitted by puncturing the coded data block coded by the channel coding of the original transmission by using a second puncturing pattern comprising fewer symbols to be transmitted than the first puncturing pattern;
> the transmission means transmit the coded data block punctured by the second puncturing pattern to the receiver;
> the receiver comprises means for combining a received coded data block punctured by the first puncturing pattern and a received coded data block punctured by the second puncturing pattern; and
> the channel decoder decodes the channel coding of the combined coded data block. [Italics by Court]

The issue was the limitation "means for detecting" which the PTAB found was indefinite since the specification "fail[ed] to identify sufficient algorithmic structure" in the specification corresponding to claim 5's "means for detecting a need for retransmission of the received coded data block." *Decision*, 2021 WL 6655659, at *8. In assessing the sufficiency of the specification to describe the "means for detecting" the Court reviewed its decision in *Noah Systems, Inc. v. Intuit Inc.*, "our case law regarding special purpose computer-implemented means-plus-functions claims is divided into two distinct groups: First, cases in which the specification discloses no algorithm; and second, cases in which the specification does disclose an algorithm but a [party] contends that disclosure is inadequate." 675 F.3d 1302, 1313 (Fed. Cir. 2012). Where the specification discloses no algorithm, the knowledge of a skilled artisan is irrelevant. *Id.* (citing *Aristocrat Techs. Austl. Pty Ltd. v. Int'l Game Tech.*, 521 F.3d 1328, 1337 (Fed. Cir. 2008)). But where the specification discloses *some* arguable algorithm, even if a party contends that the algorithm is inadequate, the sufficiency of the purportedly-adequate structure disclosed in the specification must be evaluated given the knowledge possessed by a skilled artisan.

Sierra Wireless before the PTAB relied on software protocols recited by name in the specification as examples of the corresponding structure, "ARQ" (Automatic Repeat Request) and "hybrid FEC/ARQ (Forward Error Correction/Automatic Repeat Request" (hybrid ARQ). The protocols were included in the GSM mandatory technical specifications and Sierra offered declaration evidence that "a [skilled artisan] would well understand what Forward Error Correction is and where it's conducted and would also understand what ARQ is." The PTAB evaluated the claim under *Noah* as falling within the "no algorithm" group and rejected Sierra's undisputed evidence testimony that a skilled artisan would be familiar with "well-known and commonly used error detection codes" such as CRC, as well as ARQ and hybrid ARQ and knew how to implement them. The PTAB refused to consider that knowledge because the specification itself contained no "algorithm for performing any one or more of these protocols."

The Court noted that its precedent found that patents with a total absence of structure from the specification fell within *Noah* group cases. The Court considered its cases where *some* disclosure of structure to perform the function is described in the specification. The information may be the title of an article, *Atmel Corp. v. Information Storage Devices, Inc*, 198 F.3d 1374, 1377 (Fed. Cir. 1999) (claiming a "*high voltage generating means* disposed on said semiconductor circuit for generating a high voltage from a lower voltage power supply" (emphasis added)). The Court concluded that the issue was one of whether the specification's explicit reference to protocol names is sufficient to bring the claims within the *Noah* group two. The Court held that was sufficient and the issue was whether the naming was sufficient to disclose an understood algorithm corresponding to the means-plus-function limitation. The Court held that it was error for the PTAB to categorize the case as a *Noah* group one case and refuse to allow the expert's testimony regarding the sufficiency of the disclosure.

This case is important not only for computer implemented methods as in medical devices, but also in other means-plus-function claims. Often detailed means are not found in the specification, but only a general reference to known means. Where the issue confronting the applicant or

patentee is an alleged lack of sufficient specific description of the means, expert testimony may be used to show the disclosure is sufficient.

Design Patent Claims Are Limited To The Article Identified In The Claim

BY RICHARD D. KELLY

Design patents can be important in protecting software as a medical device (SMD) as well as medical device graphical interface control panels. SMD devices are becoming important to diagnose and/or treat medical conditions such as treating attention deficit disorder (ADHD) and diagnosing Parkinson's disease. An example is USD 678,895. In a September decision, the Federal Circuit for the first time articulated the proper scope of the comparison prior art to be used in evaluating the design patent infringement analysis. In *Columbia Sportswear N. A., Inc. v. Seirus Inn. Acc., Inc.,* appeal nos. 2021-2299 and 2021-2338, the court held that to qualify as prior art for comparison purposes, the prior art design must be related to the article identified in the claim, the same as the test for validity. Before *Columbia*, what constituted comparison prior art for infringement purposes had not been clarified. In *Columbia* the claim was directed to "[t]he ornamental design of a heat reflective material as shown and described." These designs are:

The prior art '949 design was applied to fabric and not heat reflective material as in the claim. The district court in pretrial proceedings limited the comparison prior art to "wave patterns on a *fabric*."

The Court considered that the proper scope of the comparison design prior art should be applied to the same article as recited in the claim to inform an ordinary observer's comparison between the claimed design and the accused design. The Court also considered this to follow how prior decisions had viewed comparison prior art citing to *Smith v. Whitman Saddle Co.*, 148 U.S. 674 (1893) and *Egyptian Goddess, Inc. v. Swisa, Inc.*, 543 F.3d 665, 676 (Fed. Cir. 2008) (en banc). The decision limits the comparison prior art for medical devices to those that are the same type as claimed. By restricting the scope of the claims to a particular type of device such as a display for treating ADHD or a Kidney dialysis machine, one can restrict the comparison prior art. This will make it easier to prove infringement by eliminating from consideration displays to unrelated devices. This decision has the possibility to make design patents to protect software-based medical devices more valuable.

LIFE SCIENCES NEWS

Leading Legal and Judicial Scholars Warn Congress That Breaking Patents Will Not Lower Drug Prices

BY RICHARD D. KELLY

On June 7, 2023 Senator Sanders urged in an open letter to the U.S. Department of Health & Human Services to "break the patent monopoly on Leqembi" using existing laws which Senator Sanders believes give the HHS such authority, citing 28 U.S.C. § 1498. On September 28, 2023, a group comprising a former Under Secretary of Commerce Iancu, legal scholars, and retired judges responded in an open letter to selected members of Congress including Senator Sanders. The authors explained that neither § 1498 nor Bayh-Dole Act provides any support for the concept of controlling drug prices. The Bayh-Dole Act promotes the commercialization of patented inventions that may result from government funding of research, and § 1498 secures

patent-owners in obtaining compensation for unauthorized uses of their property rights by the government. A copy of the September 28 letter is located **here**.

Those of us in the life science arena need to be ready to explain to our representatives in Washington the important contributions patents have made to the nation's health to avoid permanent damage to the patent system which incentivizes our health care industry to innovate new treatments.

Novartis Survives Motion To Dismiss Its Entresto Infringement Suit Against Generic Companies

BY RICHARD D. KELLY

Novartis sued Nanjing Noratech Pharmaceutical Co., Ltd. (Noratech) and MSN Pharmaceuticals (MSN) claiming that its U.S.P. 11,096,918 ('918), was infringed under 35 U.S.C. 271 (e)(2) by the defendants filing ANDAs (abbreviated new drug application) for Novartis' drug Entresto which had sales of $4.6 billion in 2022. Noratech moved for a Rule 12(b)(6) dismissal because the Novartis' pleading "on information and belief" did not satisfy the *Twombley* and *Iqbal* pleading standards. (*Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 558 (2007); *Ashcroft v. Iqbal,* 556 U.S. 662, (2009)). MSN moved for judgment as a matter of law that it did not infringe because its product was amorphous and the '918 claims are limited to crystalline. Since the '918 patent was not in the Orange Book, neither defendant provided a well-reasoned opinion to Novartis prior to suit which should have provided information for Novartis to assert in its complaint. Instead, Novartis relied on the "information and belief" standard for the facts necessary to support its infringement allegations.

Novartis in October 2019 had filed actions against Noratech, MSN, and others asserting infringement by their ANDA products which actions were consolidated into a multi-district litigation (MDL). As part of the MDL Novartis obtained access to Noratech's and MSN's ANDAs and sample of their products but this information was subject to a protective order. In 2021 Novartis filed an infringement action against other companies for infringing the '918 patent. In that litigation the court ruled that Novartis could not use information from the MDL litigation to initiate litigation involving the same ANDAs.

In denying Noratech's 12(b)(6) motion, the court ruled that a pleading based on "information and belief" met the "relaxed pleading standard." See Belcher Pharms, LLC v. Int'l Medication Sys., Ltd., 379 F. Supp.3d 326, 331-32 (D. Del. 2019). In *Belcher* the court provided reasons why in Hatch-Waxman litigation a relaxed pleading standard was appropriate:

> Plaintiff may not know much about the details of the proposed product and may, again, not be able to plead infringement with specificity. Nor, of course, may the plaintiff go out and purchase the accused product and test it for itself since, in these cases, the product does not yet actually exist (and if samples have been created, they cannot, by law, be available for purchase).

Since the MDL protective order precluded use of the information obtained in that litigation, Novartis, for pleading purposes, could not use the information it had learned in the prior litigation in its pleadings. Thus, the relaxed standard was appropriate.

MSN motion for judgment as a matter of law failed because the court decided evidence outside of the pleadings was necessary to determine if infringement under the doctrine of equivalents existed.

This is an example of a rational application of *Twombly* and *Iqbal* where the plaintiff does not have sufficient access to information to strictly meet the standard.

NEWSLETTER EDITOR: **GRACE KIM**