OBLON

IPUPDATES

DECEMBER 18, 2023

USPTO UPDATE

USPTO Creates a New Semiconductor Technology Pilot Program

BY DAVID M. LONGO

The U.S. Patent and Trademark Office (USPTO) announced the creation of a new Semiconductor Technology Pilot Program in a Notice to be published in the Federal Register on December 1, 2023. The USPTO created this program in support of the Creating Helpful Incentives to Produce Semiconductors (CHIPS) Act of 2022, to "encourag[e] research, development, and innovation in the semiconductor manufacturing space and providing equitable intellectual property protection to incentivize investments in the semiconductor manufacturing area" by expediting examination of certain patent applications.

According to the USPTO, "[t]he pilot program permits an application that claims certain processes or apparatuses for manufacturing semiconductor devices to be advanced out of turn (accorded special status) until a first Office action is issued without meeting all of the requirements of the accelerated examination program … if the applicant files a petition to make special … meeting all of the requirements set forth in this notice."

The pilot program requires that the applicant file a petition to make special under the program for an application that "claims an invention directed to certain processes or apparatuses for manufacturing semiconductor devices." In the petition, the applicant must certify that: (1) it has a good faith belief that the claimed invention(s) meet the technology requirement of the pilot program; (2) the claimed process or apparatus is disclosed in the specification as being primarily focused on the manufacturing of semiconductor devices; (3) fast-tracking examination of the application will have a positive impact on the semiconductor manufacturing industry; and (4) the inventor(s) has(have) not been named as the Inventor(s) on more than four other nonprovisional applications in which a petition under this pilot program has been filed. Requirement (3) appears quite subjective and it is unclear how it will be scrutinized.

The pilot program is waiving some requirements of the accelerated examination program. For example, the fee for a petition to make special is being waived under this pilot program. Also, "[a]pplications accepted into the pilot program will be advanced out of turn (accorded special status) until a first Office action is issued without meeting all of the current requirements, including any extra fee payments, of the accelerated examination program (for example, the requirement for an examination support document) or the prioritized examination program (for example, the prioritized examination fee or processing fee)."

Some restrictions pertinent to the pilot program include: (a) a limitation on the number and type of claims (no more than 3 independent and up to 20 total claims, and no multiple-dependent claims), (b) an agreement to elect an invention that qualifies under the pilot program if a Restriction Requirement is issued, (c) an agreement for the duration of prosecution to not exceed the claim limits or add multiple-dependent claims, and to not cancel all claims to the elected invention or that meet the technology requirements of the pilot program, (d) a requirement to submit the application in DOCX format at the time of filing or at the time of entering the U.S. national stage; and (e) a 4-petition limitation on the number of petitions that can be filed for applications having the same inventor or any same joint inventor.

The USPTO indicated that petitions under this pilot program may be filed beginning on December 1, 2023, and that the pilot program will be available until the USPTO accepts 1,000 grantable petitions or until December 2, 2024, whichever comes first. The Notice is available **here** and **more information here**.

JPO UPDATE

Comparative Study on AI-related Inventions in 2023 by JPO and CNIPA

BY KASUMI KANETAKA

On December 1, 2023, the Japan Patent Office (JPO) announced that the JPO and the China National Intellectual Property Administration (CNIPA) jointly conducted a comparative study on AI-related inventions, to provide applicants and practitioners insights into their respective examination practices. A report of the study includes comparative study of laws, regulations, and guidelines and comparative study of example cases based on eligibility, inventive step, and enablement requirement/sufficiency of disclosure, claims supported by the description. Regarding the comparative study of example cases, below are summaries of the results. See the full report **here**. Please note that the comparative study focuses only on the examination practices for AI-related inventions. In addition, the results of this study are not legally binding on either patent office.

For the eligibility, 11 among 13 claims for 7 applications received the same judgment results from the JPO and the CNIPA. In Japan, if it is recognized that “a specific processing device or its operating method is constructed by a cooperation of software and hardware for an intended use,” an invention is eligible to be patented regardless of the technical features of the intended use. On the contrary, in China, the presence of “technical features” is crucial, and if there are no “technical features” in an invention, it is determined that the invention is not eligible to be patented. Additionally, the CNIPA considers three technical elements (technical problems, technical means, and technical effects) to judge whether the invention as a whole belongs to the technical solution described in the Patent Law.

For the inventive step, the judgment results for all 6 claims for 5 applications were the same. However, there were some differences in the judgment method. Similar to the eligibility analysis, in Japan, the inventive step is examined by considering all matters without dividing them into “technical features” and “non-technical features.” On the other hand, in China, among the “algorithmic features,” those that functionally support each other and have an interactive relationship with technical features are considered together with the technical features as a whole.

For the enablement requirement/sufficiency of disclosure, 4 cases were compared, and judgment results were generally consistent regarding AI-related inventions. Regarding the enablement requirement, the analysis method is different between the JPO and

CNIPA. Specifically, when a claim describes an invention with a generic concept and a specification describes only embodiments of "some of the subordinate concepts" included in the generic concept, the JPO would determine that the enablement requirement is not met, but the CNIPA would determine that the enablement requirement is met.

KIPO UPDATES

KIPO-CNIPA-JPO Shared Their Policy Measures to Support SMEs at TRIPO User Symposium

BY GRACE KIM

The 11th Trilateral Intellectual Property Offices (TRIPO) User Symposium hosted by Korean Intellectual Property Office (KIPO) took place on December 1, 2023 in Busan, Korea. The Symposium is a concurrent event of the annual TRIPO Heads Meeting among KIPO, China National Intellectual Property Administration (CNIPA) and Japan Patent Office (JPO), and is alternately hosted by each office. Since created, the User Symposium has offered an opportunity to the public audience and attendees from the IP community to share ideas and learn about the latest policy measures of the three offices within a given subject area.

Under this year's theme of the "Role of IP for Innovative Small and Medium Enterprises (SMEs)", KIPO, CNIPA and JPO each presented on what each office was doing to support the SMEs with creative ideas or technologies. KIPO also invited speakers from the private sectors of the three countries who gave practical presentations on how the IP-backed financing works in their country.

KIPO-JPO to Enhance Cooperation on Key Patent Issues

BY GRACE KIM

The Korean Intellectual Property Office (KIPO) and the Japan Patent Office (JPO) held the Heads Meeting on November 30, 2023 in Busan, Korea on the occasion of the Korea-China-Japan TRIPO Heads Meeting. The Commissioners of KIPO and JPO reviewed the progress in bilateral cooperation that has been actively implemented over the past six months. They reaffirmed their willingness to ensure the smooth continuation of these efforts. The Commissioners also agreed to create an expert meeting to have a close working-level communication between the two Offices on the issues that are brought by new technologies, such as whether an artificial intelligence system could be an inventor for the grant of a patent. The JPO also agreed to provide a full text of the publications of patents and utility models that KIPO does not have in its own database. When brought into practice, this is expected to help not only KIPO examiners but also external users, including enterprises and research institutions, to carry out prior art searches more accurately and effectively.

FEDERAL CIRCUIT UPDATES

Federal Circuit Explains (Again) Skinny Labels

BY RICHARD D. KELLY

On December 7 the Federal Circuit offered a confirmation of its explanation of *GlaxoSmithKline LLC v. Teva Pharmaceuticals USA, Inc.*, 7 F.4th 1320, 1333 (Fed. Cir. 2021), in *H. Lundbeck A/S, Takeda Pharmaceutical Company Limited v. Lupin Ltd.*, appeals 2022-1194, 2022-1208, 2022-

1246, slip opinion **here**, that it was limited to infringement claims under 35 U.S.C. § 271(b). In *GlaxoSmithKline* the inducement was found based on communications outside the ANDA label indications, slip opinion at p. 14. In considering the claim of infringement under 35 U.S.C. § 271(e)(2) the Court rejected the argument that any patent claiming any indication could be infringed under the statute even though the patent did not claim an indication for which approval was sought citing *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1365 (Fed. Cir. 2003). The Court noted that while *Warner* was directed to an unapproved use, subsequent decisions confirmed that it was not so limited, citing *AstraZeneca Pharms. LP v. Apotex Corp.*, 669 F.3d 1370, 1379 (Fed. Cir. 2012) ("Although [plaintiff] is correct that the patent at issue in *Warner-Lambert* claimed an off-label use for a drug, that distinction is irrelevant for purposes of § 271(e)(2).") See slip opinion at page 13.

Since communications regarding unapproved drugs is circumscribed by FDA rules, until a drug is approved, the communications required to induce infringement will not occur. Once a drug is approved or tentatively approved, then possibly inducing communications may occur. The skinny label cannot be used to omit label information applicable to all indications such as dosing, administration, safety, adverse events, and clinical data. *See Vanda Pharms. Inc. v. West-Ward Pharms. Int'l Ltd* ., 887 F.3d 1117 (Fed. Cir. 2018).

Thus, the skinny label is alive and well for § 271(e)(2) allegations but the generic must proceed with care once approval occurs.

Incorporation of an Argument by Reference Waives the Argument

BY RICHARD D. KELLY

TIn *Medtronic, Inc., v. Teleflex Innovations S.À.R.L.*, appeals nos. 2022-1721, 2022-1722, (Fed. Cir. 2023), **here**, the Federal Circuit held an argument by Medtronic incorporated by reference was waived. Medtronic had moved to enlarge its brief to 20,000 words from the 14,000 words allowed by the rules which had been denied. Apparently to save words, Medtronic incorporated its diligence argument by reference. Here, Teleflex had antedated a reference by showing a constructive reduction to practice but apparently may not have shown diligence in its activities from a time immediately prior to the reference date to its filing date. The argument Medtronic's brief comprised 2 sentences: "[I]n addressing diligence, the Board simply adopted its earlier erroneous diligence analysis in IPR2020-00132. Appx61–62. Therefore, if this Court vacates the Board's diligence holding in No. 21-2356, it should likewise vacate the Board's decision here." Since the Federal Circuit did not vacate the diligence holding in its earlier decision, this resulted in the two sentences in Medtronic's opening brief being clear incorporation by reference, *slip op.* at 7. Incorporation by reference is a violation Fed. R. App. P. 28(a)(6)." *Monsanto Co. v. Scruggs*, 459 F.3d 1328, 1335 (Fed. Cir. 2006). The Court also reiterated that "[i]t would be fundamentally unfair to allow a party to use incorporation to exceed word count." *Microsoft Corp. v. DataTern, Inc.*, 755 F.3d 899, 910 (Fed. Cir. 2014). Here, the argument sought to be incorporated comprised 4,000 words.

Recognizing that incorporation by reference was improper, Medtronic at oral argument sought to justify it because the PTAB incorporated its diligence analysis by reference to earlier decisions it had made. The Court dismissed the argument, stating "[t]he Board is certainly entitled to incorporate by reference analyses from other decisions, but that does not entitle an appellant to violate our rules when it argues before us." The Court noted that Medtronic made strategic decisions as to what material to include in its brief and chose not to develop the diligence argument. It cannot undo those decisions.

This decision underscores the dilemma faced by counsel in deciding the issues to argue in a brief and which to drop. The most important decision counsel makes in briefing or presenting a

case at trial is not what to include but what to exclude. Whether the diligence argument would have succeeded one will never know.

PTAB UPDATE

Penumbra, Inc. v. RapidPulse, Inc.

BY EVAN SMITH

The U.S. Patent Trial & Appeal Board ("PTAB") designated a portion of its decision in *Penumbra, Inc. v. RapidPulse, Inc.,* as precedential on November 15, 2023. This decision distinguishes the priority rules applicable to prior art patents cited against post-AIA patents from the priority rules applicable to pre-AIA patents. In 2015, the Federal Circuit issued an opinion in *Dynamic Drinkware, LLC v. National Graphics, Inc.,* which established that any patent being used as a prior art reference can only have the benefit of priority to a provisional application if the provisional application provided support for the claims in the prior art reference. However, the PTAB's decision in *Penumbra* upends that rule for post-AIA patents.

The PTAB held that the language of AIA 35 U.S.C. §§ 102(a)(2) & 102(d) was sufficiently different from the corresponding language in the pre-AIA §102(e) to change the requirements for a reference patent to be entitled to the benefit of a parent provisional application's filing date. As a result of the PTAB's holding, there is no longer "[a] need to evaluate whether any *claim* of a reference patent document is actually entitled to priority when applying such a reference patent as prior art." Accordingly, for consideration of priority, a reference patent only needs to meet the ministerial requirements of 35 U.S.C. §§ 119 and 120, and the provisional in question need only describe the subject matter relied upon in the reference patent as prior art.

The *Penumbra* opinion serves as an important reminder that the effective prior art date of a prior art patent may change depending on whether the patent being challenged is subject to the AIA or pre-AIA versions of the patent statute. That said, the Federal Circuit has not yet weighed in to affirm *Penumbra*'s interpretation of the AIA statute. Stay tuned until the appeals court has also addressed this interesting issue. Read our full blog post **here**.

LIFE SCIENCES NEWS

U.S. Moves Closer to Drug Price Controls With Adverse Implications for Life Science Development

BY RICHARD D. KELLY

On December 8 the National Institute of Standard and Technology published a Request for Information to allow the government to exercise its "March in Rights" for patents resulting from government supported research at universities under the 1980 Bayh-Dole Act. Copy **here**. The act was intended to encourage cooperation among industry, research institutions and government to bring innovations to market. The Act was meant to solve the problem of government patents not being commercially exploited because there were no provisions to allow for commercial gain from exploiting the patents. Under the Act the research institutions receiving federal funds could patent the results of the research and license the patents to companies to commercialize them. The Act provided for "march in" rights to confiscate a patent when the company had not made a good faith effort to commercialize the research. Former Senators Bayh and Dole in 2002 explained that their law "makes no reference

to a reasonable price that should be dictated by the government. This omission was intentional; the primary purpose of the act was to entice the private sector to seek public-private research collaboration rather than focusing on its own proprietary research." The Administration is seeking to destroy the incentives provided by the Act. The "march in" provision has not been exercised in the over 40 years since its inception.

Over 30 years ago, the NIH briefly required companies exclusively licensing its inventions to pledge to sell the byproducts at a reasonable price. Private industry walked away. In rescinding the NIH policy in 1995, director Harold Varmus said "the pricing clause has driven industry away from potentially beneficial scientific collaborations with PHS (public health service) scientists" without offsetting benefits to the public. He called it "a restraint on the new product development." The present administration either oblivious to history or intent on ignoring its lesson is going down the path the NIH tried and found wanting.

The White House issued a press release explaining its reasoning, **here**. There is no explanation as how the proposal will further the purpose of the Bayh-Dole Act. It seems that the administration is following Edmund Burke's observation that one who does not know history is doomed to repeat it.

NEWSLETTER EDITOR: **GRACE KIM**