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IP UPDATES

AUGUST 27, 2024

USPTO UPDATE

USPTO Seeks Public Feedback on The Experimental Use Exception to Patent Infringement

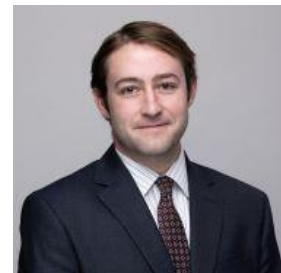
BY EVAN SMITH

On June 27, 2024, the United States Patent and Trade Office ("USPTO") published a request for comments ("RFC") in the [Federal Register](#) inquiring about the current state of the experimental use defense to patent infringement and to determine the potential value of legislative action on the issue. This RFC both supports the President's 2021 Executive Order on Promoting Competition in the American Economy and furthers a joint commitment between the United States Department of Agriculture and the USPTO's joint commitment to evaluate new proposals for incentivizing and protecting innovation in the seed and agricultural-related space.

The USPTO has provided the RFC with the intent of identifying the public's views on the impacts of the statutory use exception in particular subject areas such as the agricultural industry, wherein such a statutory change may incentivize innovation. The RFC continues by providing a series of questions which chiefly serve to identify the respondent's relationship to an industry, inquire how the current state of the experimental use exception jurisprudence may negatively or positively influence technology development in that area, and identify if and how a statutory exemption should be defined and enacted.

The comment period will be open to the general public until September 26, 2024 and should be submitted through the Federal eRulemaking Portal at <https://www.regulations.gov>.

For more on this topic, please see the Life Science's blog [here](#).



U.S. CONGRESS UPDATE

New Bill Introduced in U.S. Congress to Overturn 2006 eBay Decision

BY PHILIPPE J.C. SIGNORE, PhD

Historically, patent infringement judgments in U.S. federal courts led almost automatically to injunctive relief under 35 USC 283. This section of the patent statute provides that a court "may grant injunctions in accordance with the principles of equity to prevent the violation of any



right secured by patent, on such terms as the court deems reasonable.” The situation changed with the Supreme Court’s 2006 decision in *eBay Inc. v. MercExchange*. The *eBay* decision rejected the notion that injunctions should be generally granted upon a showing of infringement and required instead a detailed analysis based on four principles of equity: irreparable injury to the plaintiff, inadequacy of legal remedies, balance of hardships, and public interest. This decision eliminated the presumption of injunctive relief, particularly affecting non-practicing entities (NPEs). Since the *eBay* decision, many U.S. patentees have faced challenges in obtaining injunctive relief.

A new bipartisan bill, the **RESTORE Patent Rights Act of 2024**, was recently introduced in both houses of the U.S. Congress to return to the pre-*eBay* situation. The bill introduces a rebuttable presumption that an adjudged patent infringer should face injunctive relief, thus simplifying the process. Under the bill, 35 USC 283 would be amended by adding the following subsection:

If ... the court enters a final judgment finding infringement of a right secured by patent, the patent owner shall be entitled to a rebuttable presumption that the court should grant a permanent injunction with respect to that infringing conduct

Supporters argue that the *eBay* decision undermined the exclusivity of patent rights and encouraged predatory infringement by large companies. Opponents of the bill cite concerns about enabling opportunistic “holdup” situations by NPEs. Despite the bill’s bipartisan support, strong opposition and the upcoming election year make its passage uncertain.

CAFC UPDATE

CAFC Affirms Post-AIA Invalidity of Process Claims Based on Sale of Product Made by Claimed Process

BY PHILIPPE J.C. SIGNORE, PhD

The U.S. Court of Appeals for the Federal Circuit (CAFC) recently affirmed the International Trade Commission’s (ITC) decision in ***Celanese International Corp. v. ITC***, ruling that Celanese’s *process* claims were invalid due to secret sales of *products* made by the claimed process prior to the one-year on-sale bar, as codified in 35 U.S.C. §102(a). This decision followed the Supreme Court’s reasoning in ***Helsinn Healthcare v. Teva Pharmaceuticals*** (2019), rejecting Celanese’s argument that the America Invents Act (AIA) altered the on-sale bar to exclude sales of products made by undisclosed processes.



The case arose from an ITC investigation into sweeteners imported by a Chinese manufacturer, which allegedly infringed Celanese’s patents. It was undisputed that Celanese’s process was used in Europe, resulting in sales by Celanese of the sweetener more than a year before the patents’ effective filing date. The ITC found the process claims invalid, concluding that the AIA did not change the on-sale bar’s interpretation.

On appeal, the Federal Circuit emphasized that the on-sale bar has been part of U.S. patent law since the Patent Act of 1836, consistently interpreted to include sales of products made by a secret process. The court cited prior cases where patent claims were invalidated due to the commercial exploitation of a process more than a year before filing for patent rights.

Celanese argued that AIA’s change of wording in Section 102(a)(1) from “invention” to “claimed invention” and the addition of “otherwise available to the public” meant the process itself must be sold or publicly disclosed to invalidate the patent. The Federal Circuit rejected these arguments, noting that the changes were clerical and did not alter the established interpretation of the on-

sale bar. Additionally, the one-year grace period for public disclosures in Section 102(b)(1) did not apply, as Celanese's sales occurred outside this window.

JPO UPDATES



[JPO Annual Report 2024](#)

BY KASUMI KANETAKA

The [JPO Annual Report 2024](#) (in Japanese) was released in July 2024. There are several key points according to the [summary](#) (in Japanese) and the Report,

(1) Number of patent applications

The number of patent applications for the fiscal year of 2023 was more than 300,000 cases, about a 3.6% increase from the previous year.

For each fiscal year, the number of registered patents stays around 170,000 cases, and the allowance rate is getting increased. According to the JPO, these trends suggest that applicants are becoming more selective in their patent applications and that companies are shifting from quantity to quality in their intellectual property strategies.

(2) Number of patent applications from foreign countries

The number of patent applications from foreign countries for the fiscal year of 2023 is increasing similar to the previous year.

The order of applicants for the top countries/regions are the U.S., Europe, China, and South Korea.

(3) Pendency for patent examination

The average total pendency and the average First Action (FA) pendency were 13.8 months and 9.4 months, respectively.

The JPO, in 2014, set goals to shrink the average total pendency and the average FA pendency to be within 14 months and 10 months, respectively, by the end of the fiscal year of 2023. The Report shows that the goals were successfully achieved.

[Comparison on AI-Related Inventions in IP 5](#)

BY KASUMI KANETAKA

A [detailed comparison table for IP5 Offices' examination practices on AI-related inventions](#) was released in June 2024. As reported in the [July Newsletter](#), the 17th meeting of the IP 5 Heads of Office was held in June 2024, and the table was approved as a JPO-led project outcome. This new table compiles a more detailed classification of the examination cases for AI-related inventions based on the comparison of laws and examination criteria approved by IP5 last year. The materials in the table are listed in the form of hyperlinks so that users can access the latest information.

AI UPDATE

WIPO Publishes Patent Landscape Report on GenAI

BY SAMEER GOKHALE

The World Intellectual Property Organization (WIPO) published a patent landscape report on Generative Artificial Intelligence (GenAI) in July. The report describes the latest patent trends for GenAI along with insights into its future applications and potential impact. The report explores patents relating to the different modes, models and industrial application areas of GenAI. Among the highlights, the report found that China-based inventors are filing the highest number of GenAI patent applications with more than 38,000 patent families coming out of China between 2014-2023. The U.S. was second with 6,300 patent families. The report also found that the top application areas of GenAI patents are software, life sciences, and document management. The complete report can be found [here](#).



LIFE SCIENCES NEWS



May the CAFC Defer to the PTAB's Statutory Interpretation

BY RICHARD D. KELLY

United Therapeutics Corp. (UTC) has requested certiorari from the Federal Circuit's affirmance of the PTAB's decision in *United Therapeutics Corp. v. Liquidia Technologies, Inc.*, Appeal 2023-1805 (Non-Precedential) affirming the PTAB's decision in IPR202 1-00406 finding the claims of U.S.P. 10,716,793 not patentable. The issue lies in

Liquidia's modification of its proofs of invalidity in response to UTC's opposition to Liquidia's petition. UTC contends that the PTAB violated § 312 by relying on grounds and printed publications not raised in Liquidia's initial IPR petition.

The original petition relied upon the availability of two abstracts describing a clinical test asserting the abstracts were prior art under 35 U.S.C. § 102(b). UTC challenged the availability of the abstracts asserting no evidence had been offered that book containing the abstracts had been indexed in a library. Liquidia sought to remedy this deficiency with testimony by two experts that the book would have been distributed at meetings to the 18,000 to 20,000 attendees comprising a relevant audience for the technology. No direct evidence was provided by anyone having firsthand knowledge as to what was distributed at either meeting. The PTAB considered the evidence to be sufficient evidence of public dissemination.

The Federal Circuit affirmed the PTAB's decision, holding that it would defer to the PTAB's discretion if the new arguments were "not inconsistent with" the initial petition. It did not independently review the PTAB's decision to determine if 37 U.S.C. § 312 was violated but deferred to PTAB's decision it did not. UTC in its *cert.* petition argued "the petitioner's petition, not the Director's discretion, is supposed to guide the life of the litigation." *SAS*, 138 S. Ct. at 1356. As this Court has explained, the PTO does not "enjoy[] a license to depart from the petition and institute a *different* inter partes review of his own design." *Id.* at 1356. In UTC's opinion the Federal Circuit erred in not reviewing the decision *de novo* rather than deferring to PTAB that this complied with § 312 in view of *SAS*. Neither the PTAB nor the Federal Circuit provided any reasons for varying from the wording of § 312.

Although not expressly stated, the Federal Circuit should have determined *de novo* whether the modifications by Liquidia to its petition departed impermissibly from the original petition. Further,

the question as to whether UTC was prejudiced by the change does not appear to have been raised or considered. The point of the statutory provision was to avoid ambushing the patentee.

First to Publish Exception, 35 U.S.C. § 102(a)(2)/(b)(2) Safe Harbor

BY RICHARD D. KELLY

As part of the U.S. adoption of the first to file system in the AIA an exception was made for one who publicly discloses the invention less than one year before his application was filed. This allows an applicant to antedate a reference filed before his U.S. filing date but after a public disclosure of the invention. Sanho was the assignee of U.S.P. 10,572,429 ('429) to Liao which was challenged in an IPR by Kaijet over U.S. Patent Application Publication No. 2018/0165053 to Kuo. Kuo was filed December 13, 2016, while '429 was filed on April 27, 2017. Kaijet filed an IPR against the '429 patent asserting Kuo as prior art. If Kuo could be removed as prior art the IPR would fail. The '429 invention was directed to a portable USB dock which could be attached to a computer to add additional ports for attaching peripheral devices. The key part of the device was a control module for the various ports to control the attached peripherals to the computer. The controller was an essential component of the '429 patented device. The key dates are:

- November 17, 2016 (pre-filing disclosure): Liao offered the hyperdrive for sale to Sanho. The hyperdrive allegedly comprised the '429 invention.
- December 6-8, 2016 (pre-filing disclosure): Sanho placed an order for 15,000 HyperDrive units with a payment of \$153k.
- December 13, 2016 (prior art Kuo filed): Kuo filed a Taiwanese patent application (Kuo) disclosing the invention. A U.S. corresponding application filed in the U.S. in February 2017.
- April 27, 2017 (Effective Filing date of Liao): Liao filed in China, and in 2018, the corresponding U.S. application was filed which matured into the '429 patent.

There was no evidence that the controller schematic of '429 was disclosed in the U.S prior to the '429 application filing date. The issue was the safe harbor provision of 35 U.S.C. 102(b)(2)(b):

(B)

the subject matter disclosed had, before such subject matter was effectively filed under subsection (a)(2), been publicly disclosed by the **inventor** or a **joint inventor** or another who obtained the subject matter disclosed directly or indirectly from the **inventor** or a **joint inventor**;

The issue was what was the meaning of "the subject matter disclosed . . . been publicly disclosed." Sanho argued that it had the same meaning as in *Helsinn Healthcare S.A. v. Teva Pharms. USA*, No. 2016-1284, 2018 WL 1583031, at *4 (Fed. Cir. Jan. 16, 2018) (O'Malley, J., concurring in denial of rehearing en banc) (non-precedential) ("If all prior art events—i.e., all 'disclosures'—recited in § 102(a) were already public disclosures, the word 'publicly' in § 102(b) (1)(B) would be redundant, and there would be no need for a separate rule for third-party disclosures."). Thus, the Court decided that the disclosure must be public and the disclosure by Liao to Sanho had been private. The Court did not reach the question as to whether it had to also be enabling. However, if the invention included the circuitry on the controller, then an enabling disclosure would be necessary since the purpose of safe harbor was to allow disclosure to the public prior to filing, if it was not enabling it should not be considered a public disclosure, but that question must wait to another day.

NEWSLETTER EDITOR: **SAMEER GOKHALE**



Oblon | 1940 Duke Street | Alexandria, VA 22314 US

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