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IP UPDATES

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USPTO UPDATE

USPTO Issues Quick Reference Guides Regarding Updated Patent Fees

BY SAMEER GOKHALE

The United States Patent and Trademark Office (USPTO) finalized fee increases that took effect on January 19, 2025. To help address questions, the USPTO released the following Quick Reference Guides:

- ***General Quick Reference Guide*** - addresses general questions and also includes several weekend/holiday scenarios that may arise.
- ***Continuing Application Fee (CAF) Quick Reference Guide*** - addresses issues such as how to determine if a CAF is due, what is an "Earliest Benefit Date," what happens if applicants don't pay the CAF, application of the fee to reissue applications, and examples.
- ***Information Disclosure Statement (IDS) Size Fee Quick Reference Guide*** - addresses the new requirements for the IDS size fee and size fee assertion, how applicants/patent owners should count references, what happens if the fee isn't paid, and examples.

Summary of USPTO Trademark Fee Increases

BY CHRISTOPHER DONAHUE

The U.S. Patent and Trademark Office (USPTO) increased its fees for most trademark matters beginning January 18, 2025, and will increase its fees for application filings based on the Madrid Protocol beginning February 18, 2025. Among other changes the new fee schedule will influence the identification of goods and services selected by an applicant. A table of the fee increases can be found **here**.

Applications based on Section 1 (use or intent-to-use) and/or Section 44 (home country application or registration)

- The USPTO currently charges a $350 per class filing fee for a Trademark Electronic Application (TEAS standard) and a discounted fee of $250 per class for applications that meet more stringent requirements (TEAS plus). Beginning January 18 the USPTO will

charge a single filing fee of $350 per class for any application based on Section 1 and/or Section 44.
- The USPTO will charge a new additional fee of $200 per class if the identification of goods/services in that class contains an identification that is not listed in the USPTO Trademark ID Manual (online at https://idm-tmng.uspto.gov/id-master-list-public.html). That is, the only was to avoid this $200 per class fee is to comprise the identification in the class of only identifications listed in the ID Manual.
- The USPTO will charge a new additional fee of $200 per class for each additional group of 1,000 characters beyond the first 1,000 characters if the identification in that class is not comprised entirely of identifications taken from the ID Manual.
- The USPTO will charge a new additional fee of $100 per class if the application contains insufficient information, namely, if it fails to include information in any of the following categories shown **here**.
- The USPTO is increasing the fee for an Amendment to Allege Use and Statement of Use from $100 per class to $150 per class.

Applications based on Section 66(a) (Madrid Protocol International Registration)

- The filing fee for an application based on a Madrid-Protocol International Registration is being increased from $500 per class to $600 per class. The subsequent designation fee filed with WIPO is being increased from $500 to $600. The new additional fees regarding the identification of goods/services and insufficient information being charged for the Section 1 and Section 44 applications do not apply to Section 66(a) Madrid Protocol-based applications.

Post-Registration Maintenance Fees

- The USPTO is raising the fee for a Declaration of Use under Section 8 or Section 71 from $225 per class to $325 per class.
- The USPTO is raising the fee for a Declaration of Incontestability from $200 per class to $250 per class.
- Based on the above changes the new fee for a Combined Declaration of Use and Incontestability will increase from $425 per class to $575 per class.
- The USPTO is raising the fee for a renewal application under Section 9 from $300 per class to $325 per class. Accordingly, the combined fee for a combined renewal application and Declaration of Use will increase from $525 per class to $650 per class.
- The renewal fee filed at WIPO is being increased from $300 to $325.

Petitions and Letter of Protest Fees

- The USPTO is raising the fee for a Petition to the Director from $250 to $400.
- The fee for a petition to revive an application is being raised from $150 to $250.
- The fee for a letter of protest is being raised from $50 to $150.

Please feel free to contact us with any questions or concerns.

CAFC UPDATE

Federal Circuit Clarifies What Constitutes Prior Art for IPRs in *Lynk Labs, Inc. v. Samsung Electronics Co.* Ltd.

BY SAMEER GOKHALE

On January 14th, the Federal Circuit issued an opinion in *Lynk Labs, Inc. v. Samsung Electronics Co. (**see Opinion here**).* One of the issues drawing attention was whether “a published and

later abandoned U.S. patent application . . . can be applied in an IPR as a 'printed publication' under 35 U.S.C. §311(b)." This statute states that "a petitioner in an inter partes review may request to cancel as unpatentable 1 or more claims of a patent . . . only on the basis of prior art consisting of patents or printed publications." In this case, the publication at issue (U.S. Pub. No. 2004/0206970, "Martin") was directed to an abandoned application that published after the effective priority date of Lynk Labs' challenged patent (U.S. 10,687,400). Lynk Labs argued that a patent application that never issues as a patent is not a patent nor does it qualify as a printed publication when its publication date is after the effective filing date of the patent subject to the inter partes review proceeding. However, the Federal Circuit held that "the plain language of §§ 311(b) and 102(e)(1) permits IPR challenges based upon published patent applications, and such published patent applications can be deemed prior art in IPRs as of their filing date."

AI UPDATE

USPTO Releases AI Strategy Report

BY SAMEER GOKHALE

On January 14, 2025, the U.S. Patent and Trademark Office (USPTO) published "USPTO's AI Strategy" document which "aim[s] to address AI's promise and challenges across intellectual property (IP) policy, agency operations, and the broader innovation ecosystem." A copy of the report can be found **here**. The following focus areas are addressed in the report.

1. Advance the development of IP policies that promote inclusive AI innovation and creativity.
2. Build best-in-class AI capabilities by investing in computational infrastructure, data resources, and business-driven product development.
3. Promote the responsible use of AI within the USPTO and across the broader innovation ecosystem.
4. Develop AI expertise within the USPTO's workforce.
5. Collaborate with other U.S. government agencies, international partners, and the public on shared AI priorities.

President Trump Revokes Biden Executive Order on AI and Issues New Executive Order

BY SAMEER GOKHALE

In 2023, the Biden Administration issued an Executive Order (EO) that launched a large-scale effort to address emerging AI issues by adopting new guidelines, rules, and policies for various federal agencies, including the USPTO. Specifically, the Biden EO had directed the USPTO to provide guidance and recommendations on IP issues of patent inventorship, patent eligibility, and copyright authorship in view of Artificial Intelligence (AI). However, on President Trump's first day in office, he revoked the Biden EO. Then, a few days later, a new EO was released entitled "Removing Barriers to American Leadership in Artificial Intelligence," (see **here**) which calls for the development of an action plan within 180 days of the order. The new EO "revokes certain existing AI policies and directives that act as barriers to American AI innovation, clearing a path for the United States to act decisively to retain global leadership in artificial intelligence." It is not clear how the Trump EO will impact the USPTO's AI Strategy discussed above, but we will keep a close eye on the direction of the USPTO in this field under the new administration.

LIFE SCIENCES NEWS

Federal Circuit Issues Opinion in *Teva Branded Pharmaceutical Products R&D, Inc. v. Amneal Pharmaceuticals*

BY RICHARD KELLY

On December 20 the Federal Circuit decided *Teva Branded Pharmaceutical Products R&D, Inc. v. Amneal Pharmaceuticals* reported **here**. This was the third appellate decision about the listing of patents for drug delivery devices in the Orange Book. The first two decisions involved drug injector pens, *Cesar Castillo, Inc. v. Sanofi-Aventis U.S., LLC* (*In re Lantus Direct Purchaser Antitrust Litig.),* 950 F.3d 1, 3 (1st Cir. 2020), and *United Food & Commercial Workers Local 1776 v. Takeda Pharmaceutical Co.*, 11 F.4th 118 (2d Cir. 2021). Teva had listed patents on the metered drug inhaler which did not claim the active drug, albuterol sulfate. Amneal counterclaimed for an order delisting the asserted patents and for unfair competition. Teva's action in listing patents, which did not claim the active drug, was not unique as the FTC had sent warning letters in April 2024 and November 2023. See blog posts **here** and Newsletter **here**. The FDA keeps a list of the patents **here** with a notation as to the result of the notice; a few resolved the issue -- most did not. This failure to rectify the listings is surprising in that all three Circuit Court decisions involved claims of unfair competition, with *Cesar* and *United* involving claims by direct purchasers and third-party payors, and the arguments presented were contradicted by an FDA Federal Register Notice, Vol. 68, No. 117 / Wednesday, June 18, 2003 / Rules and Regulations, 36676 at 36680:

> Section 314.3 defines a "drug product" as "* * * a finished dosage form, for example, tablet, capsule, or solution, that contains a drug substance, generally, but not necessarily, in association with one or more other ingredients." The appendix in the Orange Book lists current dosage forms for approved drug products. The list includes metered aerosols, capsules, metered sprays, gels, and pre-filled drug delivery systems. ***The key factor is whether the patent being submitted claims the finished dosage form of the approved drug product***. Patents must not be submitted for bottles or containers and other packaging, as these are not "dosage forms."

While it is arguable that a patent that claims the drug plus metered inhaler or injector pen is a finished dosage form is listable since the combination is what the FDA approved, claims to the inhaler or pen per se are not, since they are not a finished dosage form. This was the holding in *Cesar.* Thus, the industry was on notice as early as 2003 that claims to a device which did not also claim the drug, were not listable. The listing statute, 21 U.S.C. § 355(b)(1)(A)(viii)(I), until 2020 provided

> (viii) the patent number and expiration date of each patent for which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug, ***and that***—
>
> (I) ***claims the drug for which the applicant submitted the application and is a drug substance*** patent or a drug product patent; or
>
> (II) claims a method of using such drug for which approval is sought or has been granted in the application. [Emphasis added]

In 2020 the statute was amended to insert after "drug substance," "(active ingredient)" and after "drug product," "(formulation or composition)." In effect, Congress amended the statute consistent with the way the First and Second Circuits had interpreted it.

The listing in the Orange Book is valuable since if a patent is listed in the Orange Book, a drug company seeking approval of a generic equivalent must provide notice (PIV Notice) to the New Drug Application holder and the patentee of the application, along with a statement why the listed patents are not infringed and/or are invalid. If the patentee sues within 45 days of the notice, the FDA approval of the generic application is stayed for 30 months. This stay can be worth hundreds or even billions of dollars. Amongst the drugs targeted by the FTC combine a GLP-1 agonist used in treating type II diabetes and for weight loss with an injector pen.

What can a drug company do to protect its combination product if its listed patents are on the FDA list?

If one or more of the listed patents describe the drug in the specification of the device patent and they have not received a PIV Notice, then they can file a reissue application either adding a claim to the device-drug combination where the drug is a claim limitation or add the drug to an existing device claim as a further limitation.

The FDA considers drug-administration device combinations to be combination drugs. Combination products are defined in 21 U.S.C. § 3.2 and includes:

> (e) A Combination product includes:
>
> > (1) A product comprised of two or more regulated components, i.e., drug/device, biologic/device, drug/biologic, or drug/device/biologic, that are physically, chemically, or otherwise combined or mixed and produced as a single entity;
> >
> > (2) Two or more separate products packaged together in a single package or as a unit and comprised of drug and device products, device and biological products, or biological and drug products;
> >
> > (3) A drug, device, or biological product packaged separately that according to its investigational plan or proposed labeling is intended for use only with an approved individually specified drug, device, or biological product where both are required to achieve the intended use, indication, or effect and where upon approval of the proposed product the labeling of the approved product would need to be changed, e.g., to reflect a change in intended use, dosage form, strength, route of administration, or significant change in dose; or
> >
> > (4) Any investigational drug, device, or biological product packaged separately that according to its proposed labeling is for use only with another individually specified investigational drug, device, or biological product where both are required to achieve the intended use, indication, or effect.

A patent to a medical device separately packaged from the drug can be listed in the Orange Book if the patent contains at least one claim to the method of administering the approved drug (a method of administration claim).

Thus, pharmaceutical companies with drugs on the FDA list of drugs having improperly listed patents should consider a reissue patent for the patents identified.

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