OBLON

IP UPDATES

FEBRUARY 28, 2025

UPCOMING EVENT

Webinar - Listing Medical Devices in Orange Book After *Teva v. Amneal*

PRESENTERS RICHARD KELLY and EVAN SMITH

On March 5, 2025, Oblon will be hosting a webinar on Listing Medical Devices in the Orange Book After *Teva v. Amneal*. Richard Kelly and Evan Smith will be the presenters.

The webinar will discuss the history of how listing medical devices in the Orange Book occurred, best practices for drafting medical device patents, how medical devices can be properly listed if they are part of a combination drug, and how to possibly repair any improper listings. An analysis of the *Teva v. Amneal* ruling is below in the Life Sciences section of the newsletter.

To register for the March 5 - 10:30am EST, click HERE.

To register for the March 5 - 8:00pm EST, click HERE.

If you have any questions about registration, email **marketingsupport@oblon.com**.

USPTO UPDATE

USPTO Releases Fee Study Report to Congress

BY SAMEER GOKHALE

The United States Patent and Trademark Office (USPTO) released a report to Congress assessing the agency's fee structures. The USPTO news release on the report highlighted the following findings and observations from the study:

- Under the current fee structure, USPTO fees do not inhibit the filing of patent applications by small and micro entities; these filers are more heavily influenced by factors external to the USPTO.
- Complementary measures such as outreach or legal assistance programs (e.g., programs highlighted in the **UAIA - Additional Regional Offices Study** and the **UAIA - Study of the Patent Pro Bono Programs**) could have a greater positive impact on small and micro entity participation rates.

- The USPTO's fee schedule structure, which defers about half of the agency's examination costs to the payment of maintenance fees, does not impact or incentivize examination and patenting decisions.
- The current USPTO fee structure, including the agency's temporary fee setting authority, is potentially superior to other models considered by the study authors because of its benefits for applicants and patentees.
- As an example of the USPTO's effective use of our fee-setting authority, the agency proactively addressed one of the study's conclusions in our latest **patent fee rule** when we set additional fees for some continuing applications that do not recover examination costs due to them expiring before all maintenance fees come due.
- There is value in providing the USPTO fee setting authority beyond the September 2026 extension included in the SUCCESS Act.

A summary of the report can be found **here**.

CAFC UPDATE

Federal Circuit Reverses District Court's Invalidity Ruling on Written Description in *Novartis v. Torrent*

BY XIAOHUA (JOYCE) GUO, Ph.D.

In a precedential opinion issued on January 10, 2025, the United States Court of Appeals for the Federal Circuit reversed a district court's ruling that had invalidated claims 1-4 of **U.S. Patent No. 8,101,659** ("the '659 patent") for lack of written description.

In the analysis, the Federal Circuit emphasized that the written description requirement mandates that a patent's specification must reasonably convey "to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." The court noted that the claims are directed to a pharmaceutical composition comprising valsartan and sacubitril administered "in combination," and not to a specific complex of these two compounds. Therefore, the specification needed to describe the combination therapy, not necessarily the complexed form. The Federal Circuit found that the specification of the'659 patent sufficiently described the combination of valsartan and sacubitril.

For more on this case, please see the Life Sciences Blog post **here**.

LIFE SCIENCES NEWS

Teva Branded Pharmaceutical Products R&D, Inc. v. Amneal Pharmaceutical

BY RICHARD KELLY

On On December 20th the Federal Circuit decided *Teva Branded Pharmaceutical Products R&D, Inc. v. Amneal Pharmaceuticals* as reported **here**. This was the third appellate decision about the listing of patents for drug delivery devices in the Orange Book. The first two involved drug injector pens, *Cesar Castillo 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 Applicants resolved the issues, but most did not. This failure to rectify the listings is surprising in that all 3 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 that is listable since the combination is what the FDA approved, claims to the inhaler or pen per se are not listable 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 statue 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 of a patent in the Orange Book is valuable for a drug a company seeking approval of a generic equivalent as they 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 thousands 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 include:

> (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.

AI UPDATE

EPO and IEA Release Report on Patents for Enhanced Electricity Grids

BY SAMEER GOKHALE

In December 2024, the European Patent Office (EPO) and the International Energy Agency (IEA) released a global trend analysis of innovation in physical and smart grids.

The key findings in the report include that grid-related patenting experienced a dramatic acceleration over the period 2009–2013. Additionally, grid-related AI

patenting grew by over 500% in the five years to 2022, and is now the most active area of patenting among enabling digital technologies, led by the United States and P.R. China.

The report can be found **here**. In an upcoming blog post on the AI Patent Blog, we will look at the report in more detail and explore some of the challenges to obtaining a patent in the field of smart grids.

FIRM NEWS

The Oblon Firm saw positive performance in 2024 in a variety of patent prosecution areas, such as the following:

-- Issued utility patents increased in 2024 over 2023.
-- Chemical utility application filings increased in 2024.
-- Increased filings in global markets such as Saudi Arabia, Korea, and Belgium.

We appreciate the continued trust from our clients all over the world, and we look forward to more mutual opportunities and accomplishments in 2025.

NEWSLETTER EDITOR: **SAMEER GOKHALE**