CHEMICAL & LIFE SCIENCE PATENTS

QUICK NEWS & PRACTICE TIPS

HARNESS IP

USPTO UPDATES

1 | USPTO FEE INCREASES:

On 19 January 2025, the USPTO implemented several fee increases. **Noteworthy Changes Are:**

i. **Utility patent applications –** 10% increase in filing fees associated with utility patent application filings (filing fee, search fee, and examination fee).

ii. **Surcharge for Continuing Applications filed more than 6 years after earliest benefit date (EBD)**
- Applications filed more than six years after its EBD require a new 2700 USD surcharge fee.
- Applications filed more than nine years after its EBD require a new 4000 USD surcharge fee.
- The EBD may be a priority claim to an earlier U.S. non-provisional application, PCT application, or international design application. The EBD is not based on a foreign (ex-US) priority application or a provisional application.

> *Practice Tip:* ***To avoid these additional fees, consider filing continuing applications less than 6 years after the EBD when possible.***

iii. **Request for Continued Examination (RCE) –** the fee for the first RCE increased to 1500 USD and the fee for the second RCE increased to 2860 USD (large entity).

iv. **Information Disclosure Statement (IDS) -** fees are now based on a number of total applicant-provided reference items (see "Information Disclosure Statement (IDS) Changes" section below for more information).

For a more in-depth summary of the patent fee adjustments CLICK HERE

2 | INFORMATION DISCLOSURE STATEMENT (IDS) CHANGES:

As of 19 January 2025, all patent applicants are required to pay a size fee when filing an IDS where the cumulative number of applicant-provided references will exceed a certain threshold (50, 100, and 200). When the cumulative number of items provided:

- Exceeds 50 but not more than 100, the fee is 200 USD.
- Exceeds 100 but is less than 200, the fee is 500 USD, less any amount previously paid.
- Exceeds 200, the fee is 800 USD, less any amount previously paid.

In addition, patent applicants are required to file a size fee assertion which clearly states either (1) that the IDS is accompanied by the appropriate IDS size fee, or (2) that no IDS size fee is required. The IDS will not be considered if the size fee (if applicable) and size fee assertion are not filed.

> *Practice Tip:* ***The IDS fees are cumulative throughout prosecution and must be updated if the number of provided references pushes the filing into the next payment tier, thus applicants should track the total number of items provided throughout prosecution to ensure proper fee payment. However, if the cumulative count is greater than a certain threshold before 19 January 2025, then the fee for that tier is not owed.***

For more information regarding these changes CLICK HERE

3 | CLIMATE CHANGE MITIGATION PILOT PROGRAM SUSPENDED:

The USPTO has suspended the Climate Change Mitigation Pilot program. An alternative way to speed up examination of a patent application is by filing a Petition to Make Special under the Accelerated Examination Program, where the petition filing fee is waived if you can state the claimed subject matter is directed to environmental quality, energy, or countering terrorism (37 CFR 1.102(c)(2)).

4 | AFTER FINAL CONSIDERATION PILOT PROGRAM 2.0 (AFCP 2.0) TERMINATED:

After an 11-year run, the USPTO's AFCP 2.0 program ended on 14 December 2024. There are still other after-final options available to patent applicants:

i. After a final office action is issued, patent applicants may submit amendments that place the application in condition for allowance or place the application in better form for appeal.
ii. Patent applicants may request an interview with the examiner to advance prosecution. Although after-final interviews are discretionary, most examiners will allow them.
iii. Patent applicants may file a pre-appeal brief conference request (PABCR) concurrently with a notice of appeal.

CASE LAW UPDATES

1 | FEDERAL CIRCUIT CLARIFIES THAT THE LEAD-COMPOUND ANALYSIS IS NOT ALWAYS NEEDED FOR FINDING A CHEMICAL COMPOUND OBVIOUS:

On 4 December 2024, in *Cytiva BioProcess R&D AB v. JSR Corp.*, 122 F.4th 876, 2024 U.S.P.Q.2d 2108 (Fed. Cir. 2024), the Court rejected Cytiva's argument that the USPTO erred by not performing a lead-compound analysis to find the product claims obvious. *Id.* at 884. The lead-compound analysis requires (1) analyzing whether an ordinary chemist would have selected a particular compound in the prior art as a lead compound (i.e., the most promising starting point for experiments), and (2) analyzing whether the prior art would have supplied a reason to modify the lead compound and make the claimed compound with a reasonable expectation of success. The Court clarified that the lead-compound analysis was not needed because the prior art expressly suggested making the G29A mutation of domain C of protein A. *Id.* The court also found the prior art taught protein A had 5 homologous domains – domains A, B, C, D, and E – so it would have been obvious to try the G29A mutation in any one of those domains. *Id.* at 885-86. For the process claims, the court determined the "binding to the Fab part of an antibody" was an inherent property of the claimed ligand with a G29A mutation so a separate analysis on reasonable expectation of success was not necessary for achieving that property. *Id.* at 886.

Takeaways:

i. A lead-compound analysis is not required where the prior art expressly suggests the proposed modification and/or where the obvious-to-try rationale may be used.
ii. An inherent property of a compound may satisfy the reasonable expectation of success requirement for obviousness where the inherent property naturally results from the prior art combination.

2 FEDERAL CIRCUIT INTERPRETS ORANGE BOOK LISTING STATUTE AND AFFIRMS DELISTING OF DEVICE PATENTS:

On 20 December 2024, in *Teva Branded Pharm. Prods. R&D, Inc. v. Amneal Pharms. of N.Y., LLC,* 124 F.4th 898, 2024 U.S.P.Q.2d 2210 (Fed. Cir. 2024), the Court held that device patents must claim at least the active ingredient to be properly listed in the Orange Book, which publishes New Drug Applications (NDAs) approved by the FDA. To list a patent in the Orange Book, that patent must claim the drug for which the applicant submitted the NDA and for which the NDA was approved. And to claim that drug, the patent must claim at least the active ingredient. Thus, patents claiming just the device components of the product approved in an NDA do not meet the listing requirement of claiming the drug for which the applicant submitted the NDA. The Court found that Teva's claims did not particularly point out and distinctly claim what was approved (ProAir® HFA with albuterol sulfate as the active ingredient).

Takeaways:

i. For both current and potential Orange Book listings, periodic and regular careful review and consideration of whether to maintain and/or list patents must be taken. Consider whether a good argument can be made as to why the patent is Orange Book-listable.

ii. For device patents to be Orange Book-listable, claim the active ingredient. The active ingredient may be claimed generically (broadly), more narrowly (mid-scope) and specifically (species).

CLS PRACTICE GROUP UPDATES

1 The CLS practice group welcomes Caley Bennett (Detroit) and Jeffrey Lin (St. Louis) as new Associates.

2 Former Technical Specialist, Jordyn Grawe (St. Louis), has been elevated to Patent Agent.

3 CLS group members plan to attend the following upcoming conferences. Please reach out to plan a meet-up!

i. May 13-15, 2025: American Intellectual Property Law Associate (AIPLA) Spring Meeting; Minneapolis, MN – Michael Varco

ii. May 17-21, 2025: 147th Annual Meeting of the International Trademark Association (INTA) – Bob Siminski

iii. June 23-26, 2025: 7th International Symposium on Bioremediation and Environmental Biotechnology; Boston, MA - Jordyn Grawe

iv. June 25-26, 2025: Carbon Capture/Hydrogen/Ammonia Tech Expo North America; Houston, TX – Michael Gamble

v. June 26-27, 2025: 14th Annual Leadership Council on Legal Diversity (LCLD) Alumni Leadership Symposium; Minneapolis, MN - Alex Chang

vi. July 17-18, 2025: 50th Annual Institute of Continuing Legal Education (ICLE) Intellectual Property Law Institute, Grand Traverse Resort; Acme, MI

vii. September 7-9, 2025: Intellectual Property Owners Association (IPO) Annual Meeting; San Diego, CA – Michael Gamble, Leanne Rakers, Colleen Shovlin

CONTRIBUTORS:

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