

INVALIDITY SEARCH

Abaloparatide Drug



Overview

We conducted an **Invalidity** Search focused on "**abaloparatide drug**". The client requested an invalidity search for a US patent detailing an abaloparatide formulation with specific criteria, including the presence of beta-Asp10, pH range, concentration, and a method for establishing suitability. Additionally, HPLC and/or UPLC methods were employed for detection, and the product underwent refrigerated storage for 23 months followed by room temperature storage for one month.

Main Focus

1. Took into account **the most recently granted claims** for the search process.
2. Examined the **notice of allowance** to gain a precise understanding of the **novel aspect** and to determine which **specific points required accurate and informed searching**.
3. Concentrated on identifying the pivotal components of the patent in question, which encompass the method for assessing the compatibility of a formulated **abaloparatide** drug product, ensuring it contains less than or equal to **5% w/w beta-Asp10** of the total peptide content, employing HPLC and/or UPLC detection methods.

Activities Performed

1. To begin, we conducted a **comprehensive analysis** of the subject patent, delving into its abstract, background, scope of invention, detailed description, provided examples, and accompanying images.
2. We thoroughly reviewed the **file wrapper**, office actions, initial claims, amended claims, examiner's requisitions, non-final rejections, and the results cited by the examiner, along with the arguments and amendments presented by the applicant.
3. Following this, we carefully examined **the examiner's search strategy** and **the notice of allowance**.
4. Once we had a firm grasp of the intricacies of **the invention and scrutinized its specific or innovative aspects** through the file wrapper, we proceeded to initiate the search process.
5. Throughout our search, we implemented essential foundational procedures, which involved gaining a comprehensive understanding of the invention and identifying relevant keywords, including their synonyms and **technical equivalents**.

Search Strategies

1. We have applied different search strategies like, keyword (specific keywords and their synonyms) based search, Class (IPC, CPC, US, F-term) based search, keyword + class based search, major assignees based search, inventors based search and their combination such as keyword + IPC/CPC, keyword + top assignee, keyword + top Inventors etc.
2. We have also performed citation and similar search for the prior arts that we got in our searching.
3. We used various search terms such as Abaloparatide, Parathyroid Analog, PTHRP, Parathyroid Hormone-Related Protein, BIM 44058, Tymlos, BA058, Abaloparatide Related Peptides, Abaloparatide, Derivative and BETA-ASP-Abaloparatide, ASP, Aspartic Acid, BETA-ASP10, BETA Isomer, BETA-ASP10, Abaloparatide, "B-ASP10" or "3-HASP" OR BETA-HASP.etc. Subsequently, our search yielded valuable references from these identified search terms.

Patent Databases

1. Utilized various paid and free patent databases: ORBIT, Patsnap, Google Patent, and native databases like PAJ, SIPO, INVENES, DPMA, TIPO, LENS.ORG, and more.
2. Conducted comprehensive searches across non-patent databases: Google, Google Scholar, Science Direct, and PubMed, covering journals, research papers, clinical trials, and regulatory publications.
3. Utilized Exact and substructure-based queries in databases like Scifinder and ORBIT.
4. Explored publicly accessible sources such as SURECHEM, PUBCHEM, and CHEMSPIDER etc.
5. Performed searches in the Orange Book and Purple Book for additional information.

Efforts Made

1. Due to the heightened complexity of this invalidity matter, despite conducting thorough searches across multiple databases, we were unable to locate a single reference that directly addressed the novel element of the patent in question. In response, we invested additional effort and explored unconventional approaches to challenge the novelty. Consequently, we implemented fundamental procedures, including gaining a comprehensive understanding of the invention, to address this challenge effectively.
2. We pursued our secondary approach, involving combinations of search results, in an effort to encompass the claimed invention comprehensively.
3. Ultimately, we successfully identified nine related prior art references that substantially negated the inventiveness of the subject matter. These references disclosed one or more key features related to the subject of the search. We ensured the coverage of all five to six key features in several of these prior art references. For example, Prior art 1 revealed key features 1 and 2, Prior art 2 unveiled key features 1 and 3, while Prior art 3 encompassed key features 1, 2, and 4. Likewise, Prior art 4 disclosed key features 1, 4, and 5, and Prior art 6 brought to light key features 1 and 6, and so forth.
4. Our findings clearly illustrate combined reading of these mapped references disclose the key features of the target claims and it fails to establish novelty and non-obviousness.



Search for Drug Analogous

In our quest to uncover the most relevant references, we conducted a specialized database (STN) search focused on peptide analogs of parathyroid hormone-related protein (PTHrP), specifically aiming to encompass the structural aspects of abaloparatide and PARATHYROID ANALOG.

Teaching Susggestions

1. These nine prior art references collectively demonstrate the uniqueness of the search. The 1st reference involves PTHrP, aspartic acid, and buffers using HPLC. The 2nd details an abaloparatide analog with $\alpha \rightarrow \beta$ substitution and phosphate buffer saline. The 3rd deals with methyl alanine residue substitution. The 4th centers on abaloparatide formulations for bone fracture prevention. The 5th discusses $\alpha \rightarrow \beta$ substitution at positions 17 and 19. The 6th mentions PTHrP or abaloparatide with TRIS buffer. The 7th covers AAV methods and acidic residue substitutions. The 8th explores polymeric abaloparatide using PBS. The 9th focuses on PTHrP1-34 analog, abaloparatide for osteoporosis treatment. A comprehensive review of these references reveals essential aspects of the target claims.
2. While combining the results, we made a deliberate effort to maintain the alignment of the chosen references within the same domain or same preamble. Furthermore, we verified that these references were not part of the exclusion list associated with the subject patents. This list excludes prior arts like backward/known citations of the subject invention, their family members, and direct family members of the subject patent.

Challenges

1. Identifying and selecting prior art using the same element claimed in the subject patent.
2. Since the prior art does not directly disclose the subject invention, we establish a correlation by equating the terminology and provided references in combinations.
3. Mapping information from translated text sourced from Espacenet for non-U.S. jurisdictions due to the diversity of languages.
4. We embarked on developing new concepts and broadened our search parameters to expedite the process.
5. We've examined data sourced from the priority document associated with a US patent.