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Invalidity Search

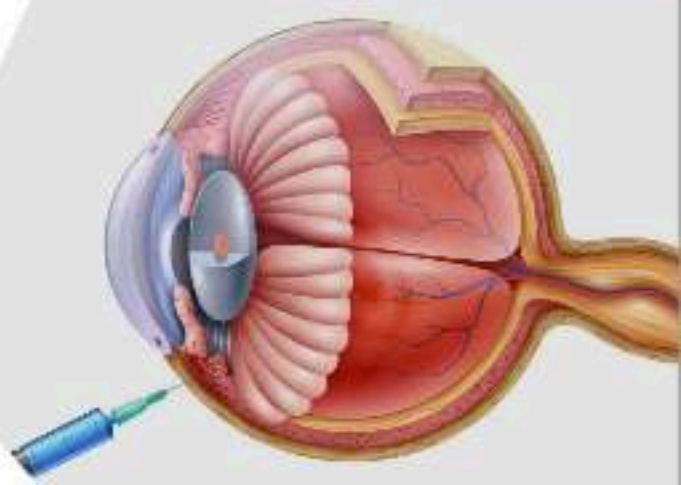
Anti-VEGF Agents

INTRODUCTION

We have recently performed an Invalidity Search based on "Anti-VEGF agents". The client asked for an invalidity search for a Canadian patent disclosing the use of an anti-VEGF agent in therapy for the treatment of neovascular (wet) age-related macular degeneration (AMD) in a subject to improve the visual acuity, wherein the subject has an AMD lesion, active choroidal neovascularization (CNV) affects less than fifty percent of the total area of the subject's lesion, the anti-VEGF agent is aflibercept. Further, the size of the active CNV lesion as well as the total lesion size is determined using Fluorescence Angiography (FA).

ACTION TAKEN

- Checked all office actions, examiner's requisitions, and applicant's arguments and amendments.
- Applied basic fundamental procedures, including:
  - ✓ In-depth understanding of the subject matter.
  - ✓ Extraction of relevant keywords, synonyms, and technical equivalents.
- Initiated the search after comprehending the invention.
- Analysed the novel aspect of the subject matter which was the lesion size for treatment.



POINT OF FOCUS

- The key arguments and modifications outlined in the office actions were observed. It was observed that, from date of filing to date of notice of allowance, the Applicant modified its initial claims, which had been based on the assertion of multiple VEGF agents, and reduced them to a single VEGF agent, namely aflibercept.
- After a comprehensive analysis of the file wrapper, we identified novel aspect and initiated the process of searching.
- The patent claimed the priority date from its PCT application.
- Focused on identifying key elements of the subject patent, i.e. use of an anti-VEGF agent (aflibercept) for treatment of a lesion in a subject's eye with wet age-related macular degeneration (wAMD) occupying less than fifty percent of total lesion size.
- Considered the latest granted claims for the search.

CHALLENGES

- The latest granted claims of subject patent have 18 independent claims.
- We were continually coming across references discussing other anti-VEGF agents for treating the CNV lesion.
- Most of the relevant literature was published by the applicant and mentioned in the office actions arguments.

SEARCH STRATEGIES

During our search, we prepared some key elements based on the subject matter and followed search strategies, such as:

- Keyword-based search (specific keywords and their synonyms).
- Class-based search (IPC, CPC, US).
- Keyword + class-based search.
- Major assignees-based search.
- Inventors-based search.

PATENT DATABASES

Utilized various paid and freely available patent databases, including:

- Orbit database
- PatSnap database
- Espacenet, WIPO, USPTO, CIPO, JPat, CNIPA
- Google Patent

We searched in different jurisdictions databases like IP Australia where the claimed invention has been patented.

CLINICAL TRIALS DATABASES

- We checked clinical databases as the applicant mentioned in the office actions that the claims are novel and non-obvious over the cited prior art due to the distinct patient population defined in the claims and the new uses of anti-VEGF agents in that patient population, which were not previously known, suggested or enabled.
- Thus, we searched for relevant information in clinical trial databases:
  - ✓ ClinicalTrials.gov, EU Clinical Trials Register, International Clinical Trial Registry.

NON-PATENT DATABASES

Leveraged non-patent databases like Google/Google Scholar, Science Direct, PubMed, etc.

RELEVANT DISCLOSURES

- Both prior arts disclosed the use of Aflibercept (VEGF TRAP) for the treatment of wet age-related macular degeneration (wAMD) CNV lesions in a patient's eye.
- The specific condition mentioned in both cases was when the CNV lesion occupied no more than fifty percent of the total lesion size.
- The non-patent prior art focused on clinical trial to determine the efficacy and safety of multiple-dose administration of VEGF Trap-Eye in patients with CNV lesions.
- The relevant references, alone or combined, disclosed all elements of the new claims, especially use of aflibercept to treat patients with active CNV <50%.

FINDINGS

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ADDITIONAL PRIOR ART

- The use of other VEGF antagonists for addressing similar issues.
- An approach to treating wAMD based on the thickness or volume of the CNV lesion rather than its size.
- Most of the clinical trials and related literature, we came across were sponsored by the applicant in collaboration with the drug manufacturer.

IDENTIFIED PRIOR ARTS

Discovered two relevant prior arts during the exhaustive search:

- One was a patent prior art.
- The other was a non-patent prior art.

ADDITIONAL

We have also performed an additional search (citation and similar search) with the findings we identified. Subsequently, we compiled a well-organized report based on this search and delivered it to the client. The client responded with great satisfaction, expressing their appreciation for the quality of the prior arts and the report's format, as well as acknowledging the effort we invested in the search.

VISIONARY BREAKTHROUGHS

The European Commission announced the approval of Yesafili, an aflibercept biosimilar by Biocon Biologics indicated for ophthalmic conditions like neovascular age-related macular degeneration, macular edema, and myopic choroidal neovascularization.

The higher dose of aflibercept, Eylea HD has been approved by FDA for various ophthalmic conditions such as wAMD, diabetic retinopathy and diabetic macular edmea.

EXPERTISE

She is a highly skilled biotech- nology expert, led the team with her profound knowledge of various biotech-nological fields. Her mastery of molecular biology, biopharmaceuticals, statistical analysis, and computational biology significantly contributed to the success of this complex invalidity search.

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