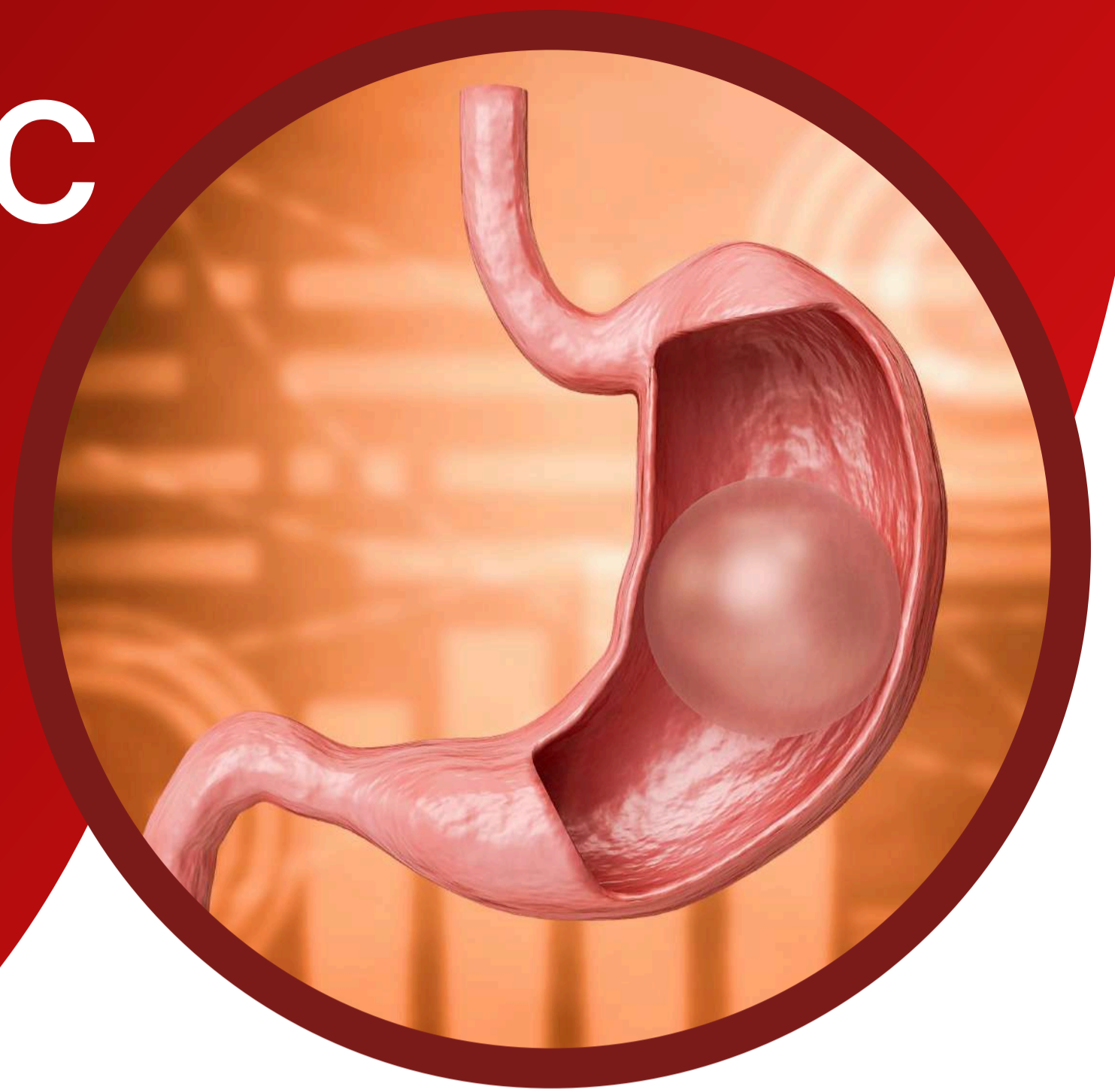


INTRAGASTRIC DEVICE INVALIDATION

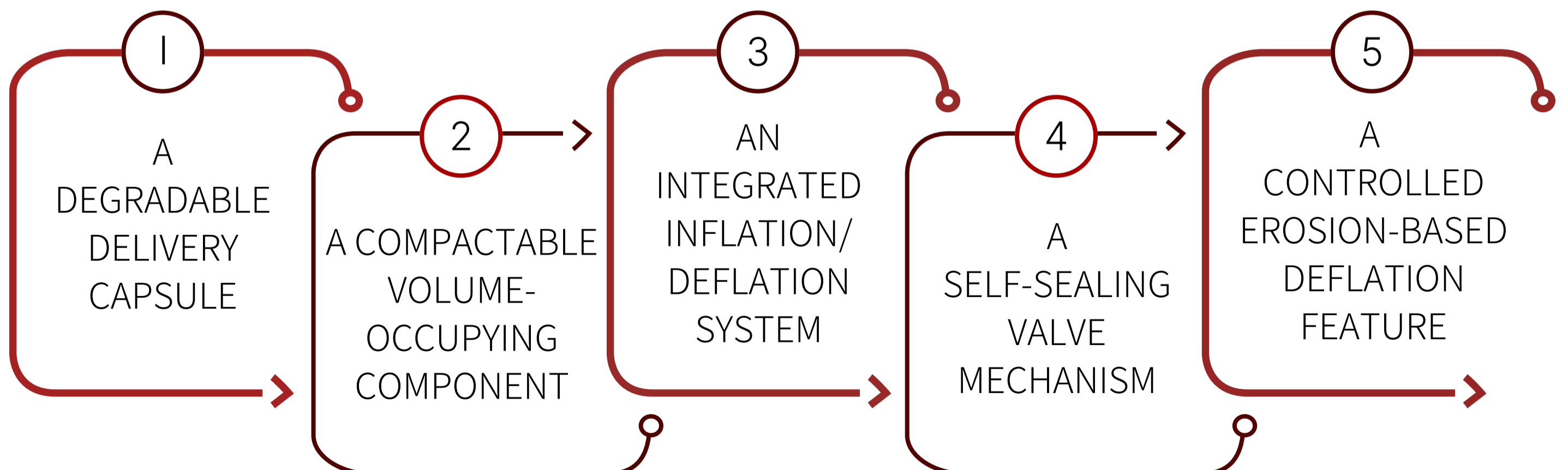
CASE STUDY



The global obesity epidemic continues to drive the need for effective, minimally invasive treatment options. Intra-gastric devices serve as an essential bridge between conservative management and invasive surgical interventions. This case study examines an innovative intra-gastric volume-occupying device system designed to address key challenges in minimally invasive obesity treatment.

OVERVIEW

Traditional intra-gastric balloons, while effective, have faced challenges related to deployment, patient comfort, and removal procedures. The subject invention center on a swallowable device system that occupies gastric space through a unique inflation mechanism. This novel system introduces several technological advances to overcome limitations, including:



SCOPE OF ANALYSIS

This invalidity analysis examines prior art and technical developments in related fields, including:

- ▶ Intra-gastric balloon systems
- ▶ Drug delivery capsule technology
- ▶ Medical valve systems
- ▶ Controlled release mechanisms
- ▶ Biocompatible materials

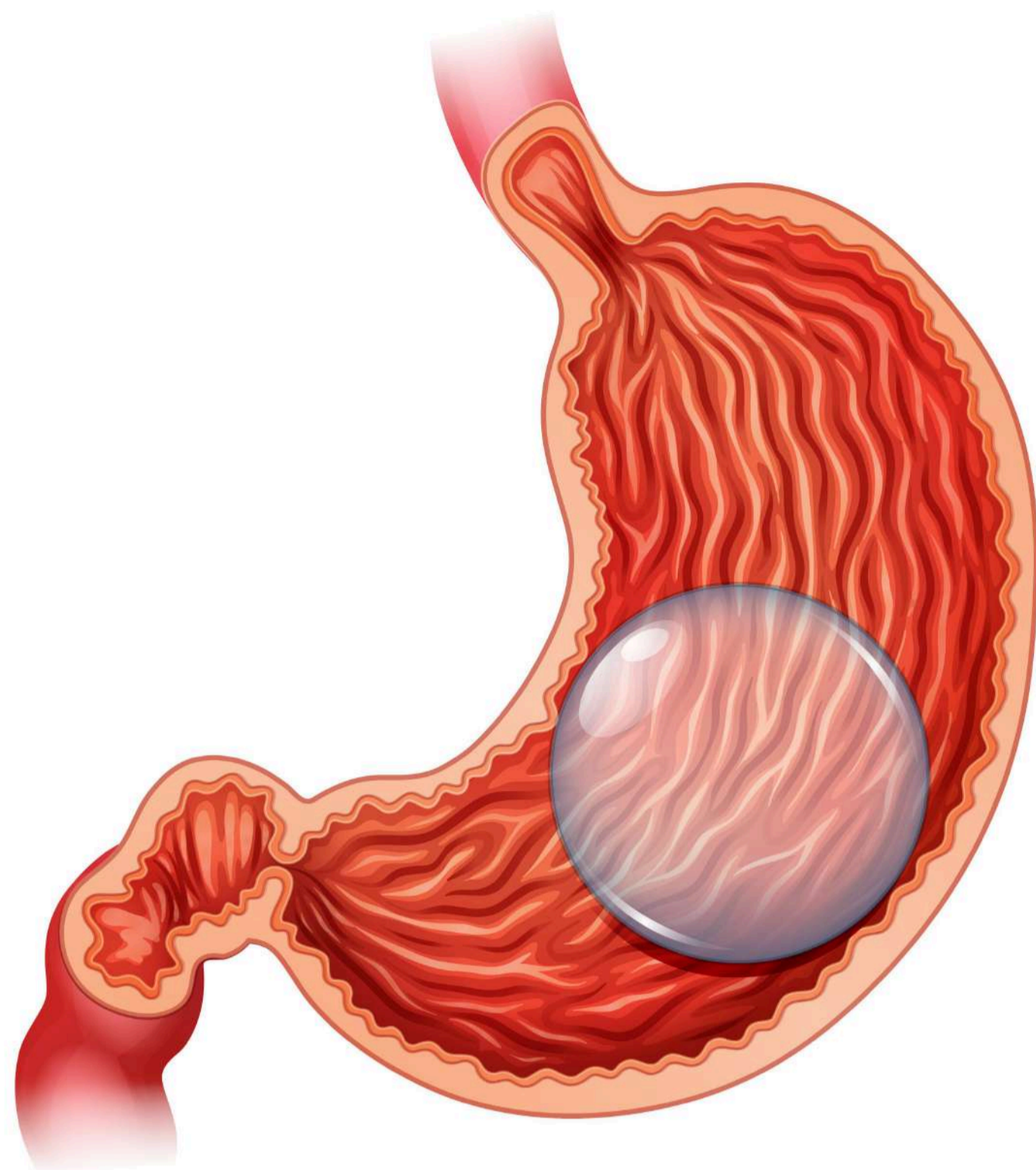
ACTION TAKEN

- 🔍 Reviewed the file wrapper, office actions, examiner's requisitions, and applicant's arguments and amendments.
- 🔍 Applied fundamental procedures, including:
 - Gaining an in-depth understanding of the subject matter.
 - Extracting relevant keywords, synonyms, and technical equivalents.
- 🔍 Initiated the search after understanding the invention.
- 🔍 Analyzed the novel aspects of the invention, particularly the degradable delivery capsule.
- 🔍 Examined the notice of allowance to determine specific points for focused searching.

SEARCH METHODOLOGY

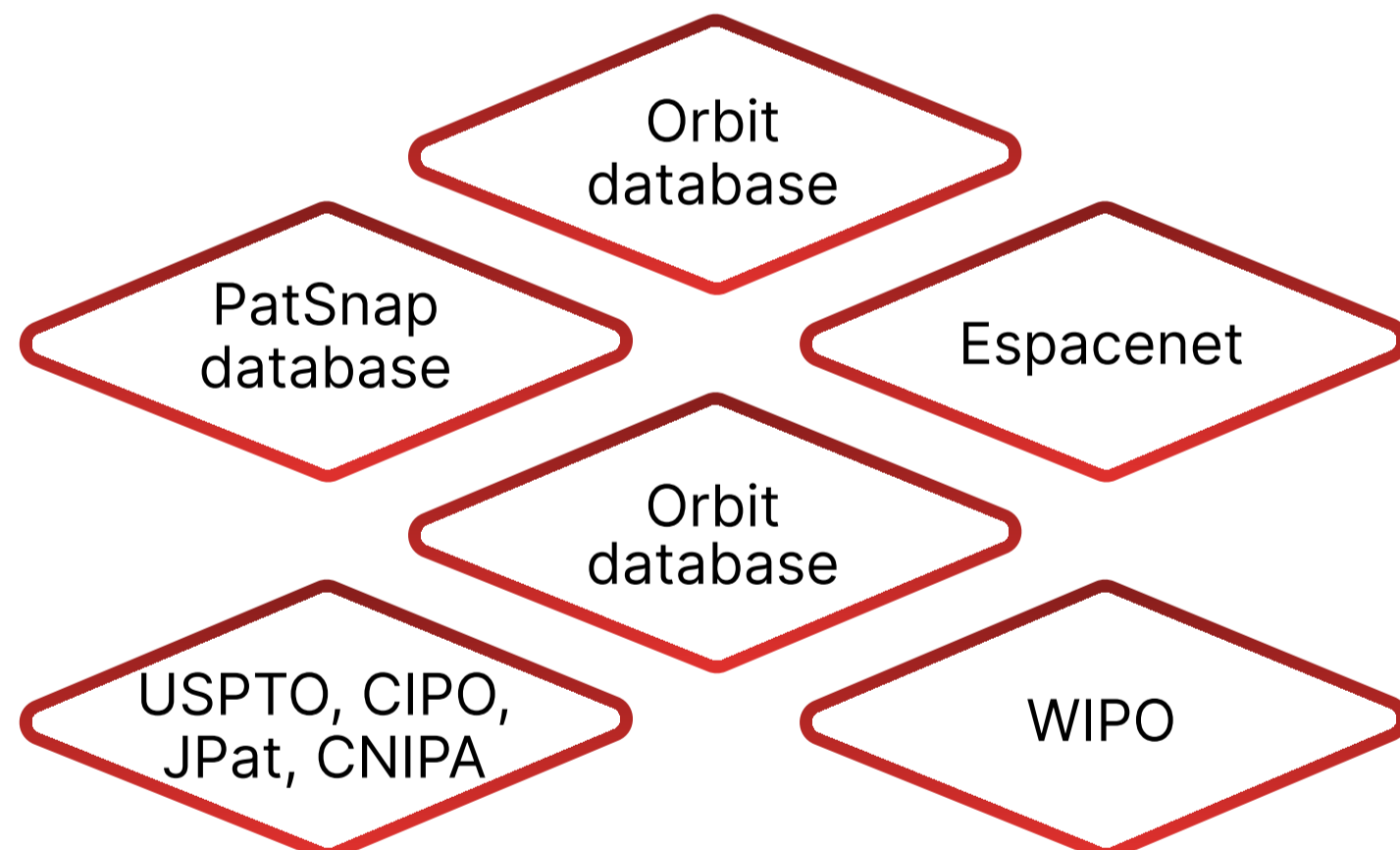
We employed several strategies during our search, including:

- ▶ **Keyword-based search:** Specific keywords and synonyms.
- ▶ **Class-based search:** Using IPC, CPC, and US classifications.
- ▶ **Keyword + class-based search.**
- ▶ **Major assignees-based search.**
- ▶ **Inventors-based search.**



PATENT DATABASES

We utilized various paid and freely available patent databases, such as:



We also searched jurisdictional databases like IP Australia, where the claimed invention has been patented.

CLINICAL TRIALS DATABASES

Given the applicant's references to clinical trials in the office actions, we explored:

- ClinicalTrials.gov
- EU Clinical Trials Register
- International Clinical Trial Registry

NON-PATENT DATABASES

We used non-patent databases such as Google Scholar, Science Direct, and PubMed to gather relevant information.

APPROACH TO FINDING REFERENCES

Our search focused on the intragastric volume-occupying device system, emphasizing degradable swallowable capsules, volume-occupying components, and catheter systems for inflation

- ▶ We identified one reference describing an apparatus triggered by intestinal responses, incorporating an inflatable gastric balloon with an osmotically active membrane that self-deflates due to an imbalance between inflation fluid and intestinal contents.

Based on feedback on the interim results, we conducted an additional search on the missing concept: "the balloon self-deflates due to the erosion of a valve from exposure to the liquid within the balloon." This search involved queries like "balloon deflation valve 'inside liquid'."

IDENTIFIED REFERENCES AND COMBINATION ANALYSIS

The subject invention features a capsule designed for natural swallowing and gastric degradation. It contains a volume-occupying component with a composite wall, a self-sealing valve system, and a deflation mechanism involving a septum with a lip or ring, moisture-erodible material, and moisture-absorbing expandable material.

1. EPXXXXXXA1

- Describes a gastric balloon with an osmotically active membrane that self-deflates due to an imbalance between inflation fluid and intestinal contents.
- The subject invention lacks structural features, such as the septum with a lip or ring and the moisture-absorbing expandable material, which differentiates the deflation mechanism.

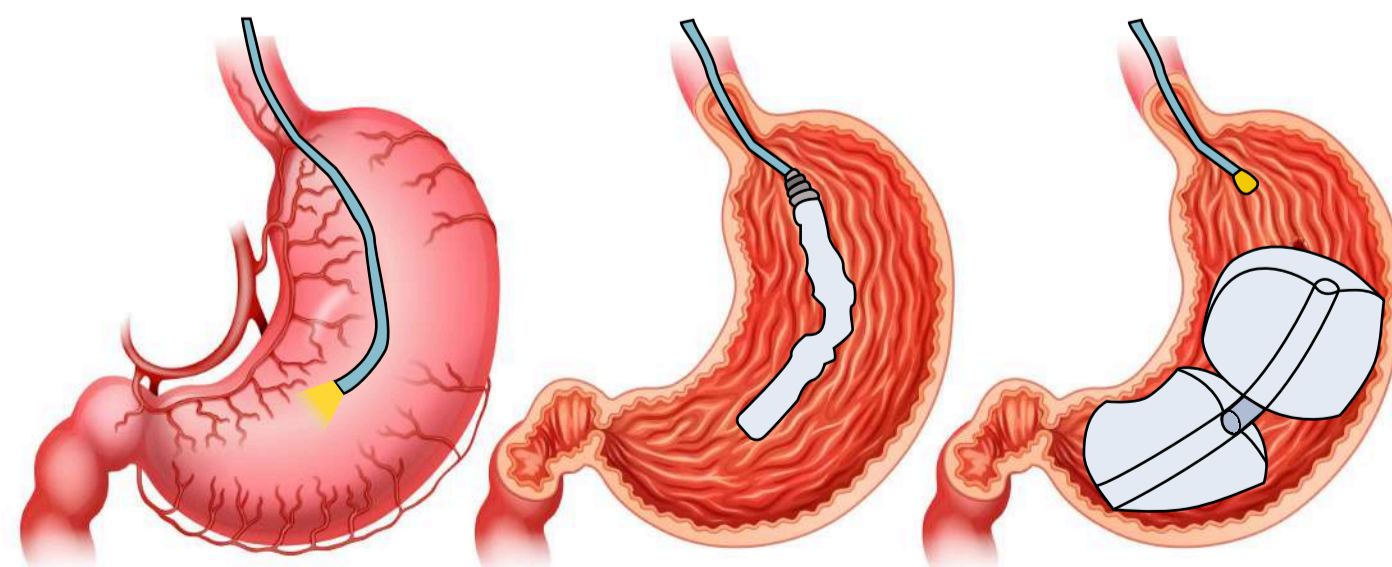
2. EPXXXXXXA2

- Describes a swallowable drug delivery device using a balloon with a biodegradable deflation valve.
- Although it shares functional similarities, it operates in a different environment (small intestine) and lacks the coordinated erosion and expansion mechanism tied to the septum lip or ring.

FAMILY MEMBERS OF EPXXXXXXA1

- Published before the cut-off date, these references disclose a biodegradable deflation valve but differ in purpose and structural details.

While the purpose of EPXXXXXXA1 is drug delivery to the small intestine, its inflating and deflating mechanisms resemble the subject invention. A skilled person might combine the deflating valve teachings of EPXXXXXXA2 with EPXXXXXXA1.



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CONCLUSION

This invalidity case study comprehensively evaluated the novelty and anticipation of the subject intragastric volume-occupying device system. The identified references, including EPxxxxxxA1 and EPxxxxxxA2, offered insights into prior art that share functional similarities with the claimed invention. The combination analysis revealed a skilled person might integrate teachings from these references such as self-deflation mechanisms & biodegradable materials.

TIP

Dissect the Claims: Focus on independent claims and their key elements, as they form the basis of the invention's scope.

- Consider whether multiple prior art references could be combined to render the invention obvious to a person skilled in the art.
- Use cited references and citing documents of relevant patents to uncover additional prior art.

EXPERT

She is a highly skilled biotechnology expert, led the team with her profound knowledge across various biotechnology fields. Holding a Master's degree in Biotechnology from the University of Melbourne, Australia, and with over 5 years of hands-on experience, she has demonstrated a deep understanding of molecular biology, microbiology, biopharmaceuticals, statistical analysis, and computational biology. Her expertise played a crucial role in the success of this complex FTO search.



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