



Innovation in the Pharmaceutical Market: An Analysis of the Patents of Monoclonal Antibodies

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BACKGROUND

Targeted therapies such as monoclonal antibodies (mAbs) are revolutionizing healthcare. These laboratory-made immune system proteins can be used to treat various diseases. However, they usually enter the market at very high prices. One of the reasons for this might be associated with the market structure and concentration.

OBJECTIVE

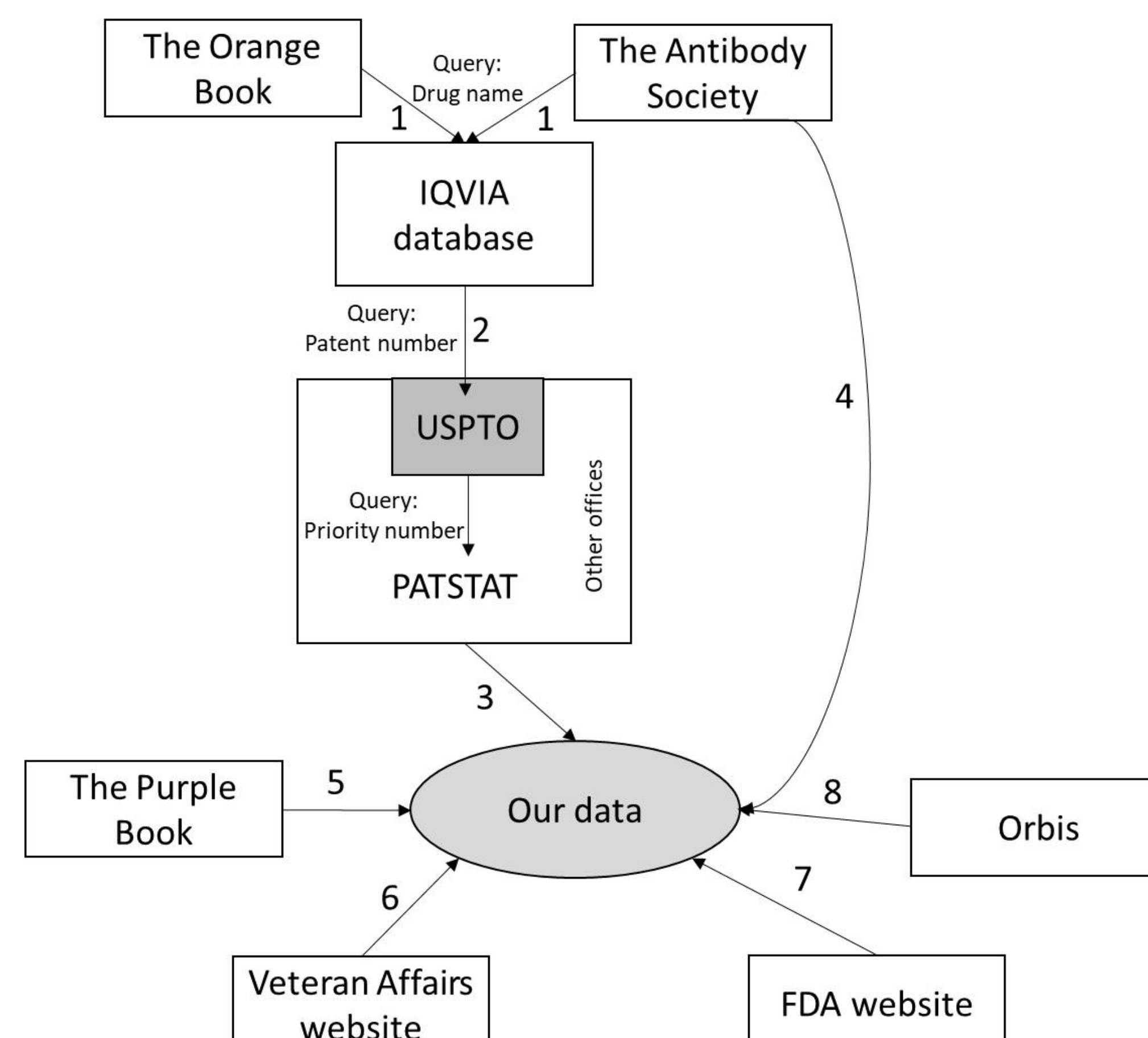
This study aims to characterize the market for mAbs through patent analyses.

METHODS

A quantitative analysis of patents was conducted. The starting point was the patents associated with mAbs approved until 2019 by the FDA identified in the IQVIA database of patents (**Figure 1**).

Other databases included in the study were the Antibody Society, the Purple Book, the Orange Book, the FDA website, the Veteran Affairs website, and ORBIS.

Figure 1. Database construction

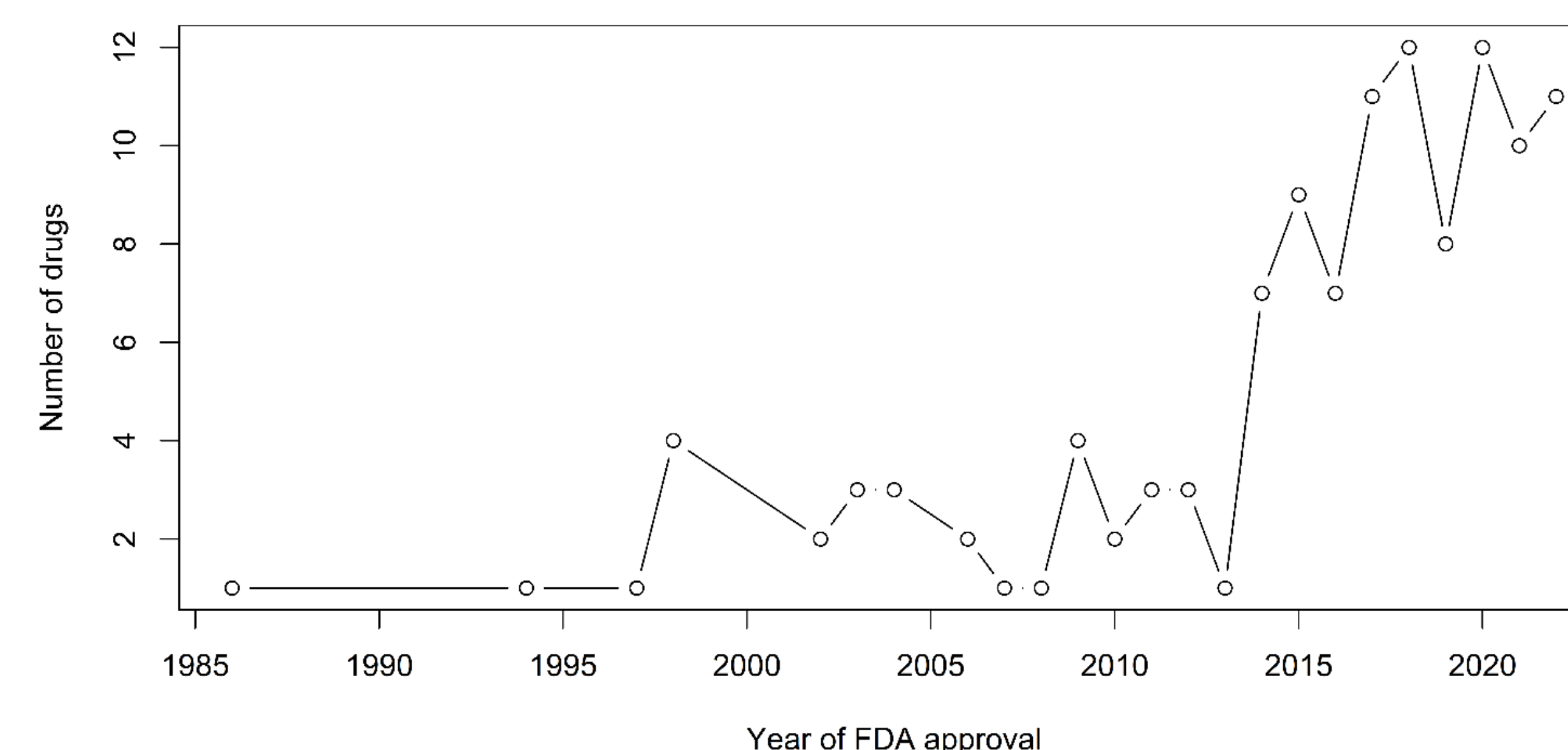


The data analysis was divided into five sections: (i) mAb patents, (ii) mAb indications and uses, (iii) patent holders and producers, (iv) indicators, and (v) network analysis.

RESULTS

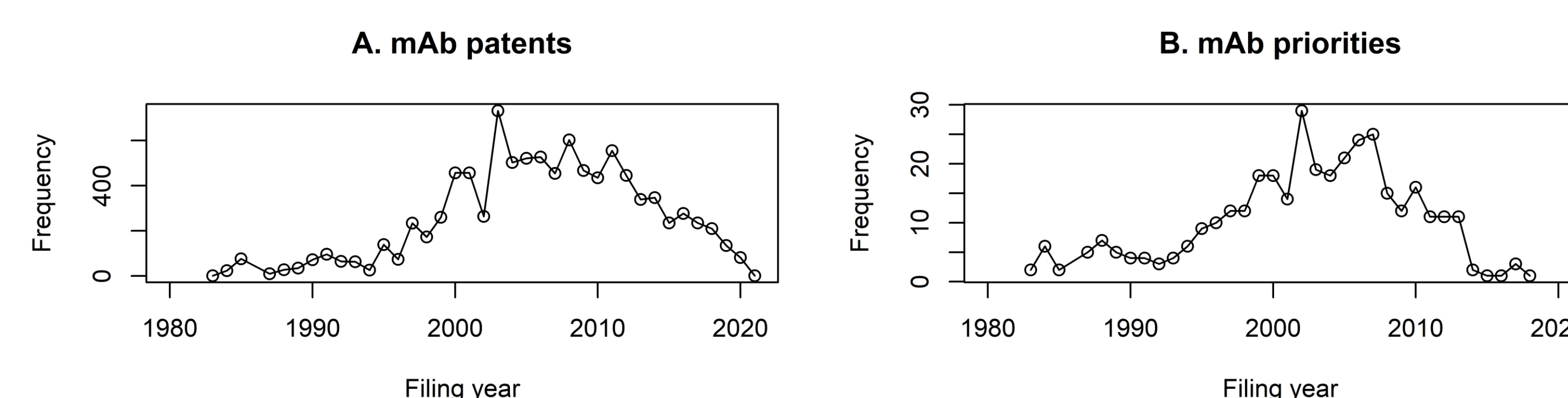
The study sample included 63 mAbs. The number of molecules approved yearly by the FDA has increased since the market's inception (**Figure 2**).

Figure 2. Number of new monoclonal antibodies registered yearly by the FDA.



These mAbs were associated with 1,732 unique patents. Most patents were related to drugs, being described as “New Use Related to Main Indication” (N=395), “Molecule Patents” (N=328), and “Dosing Regimen/Administration Conditions” (N=173). **Figure 3** demonstrates very little innovation in the market for mAbs before the mid-1990s.

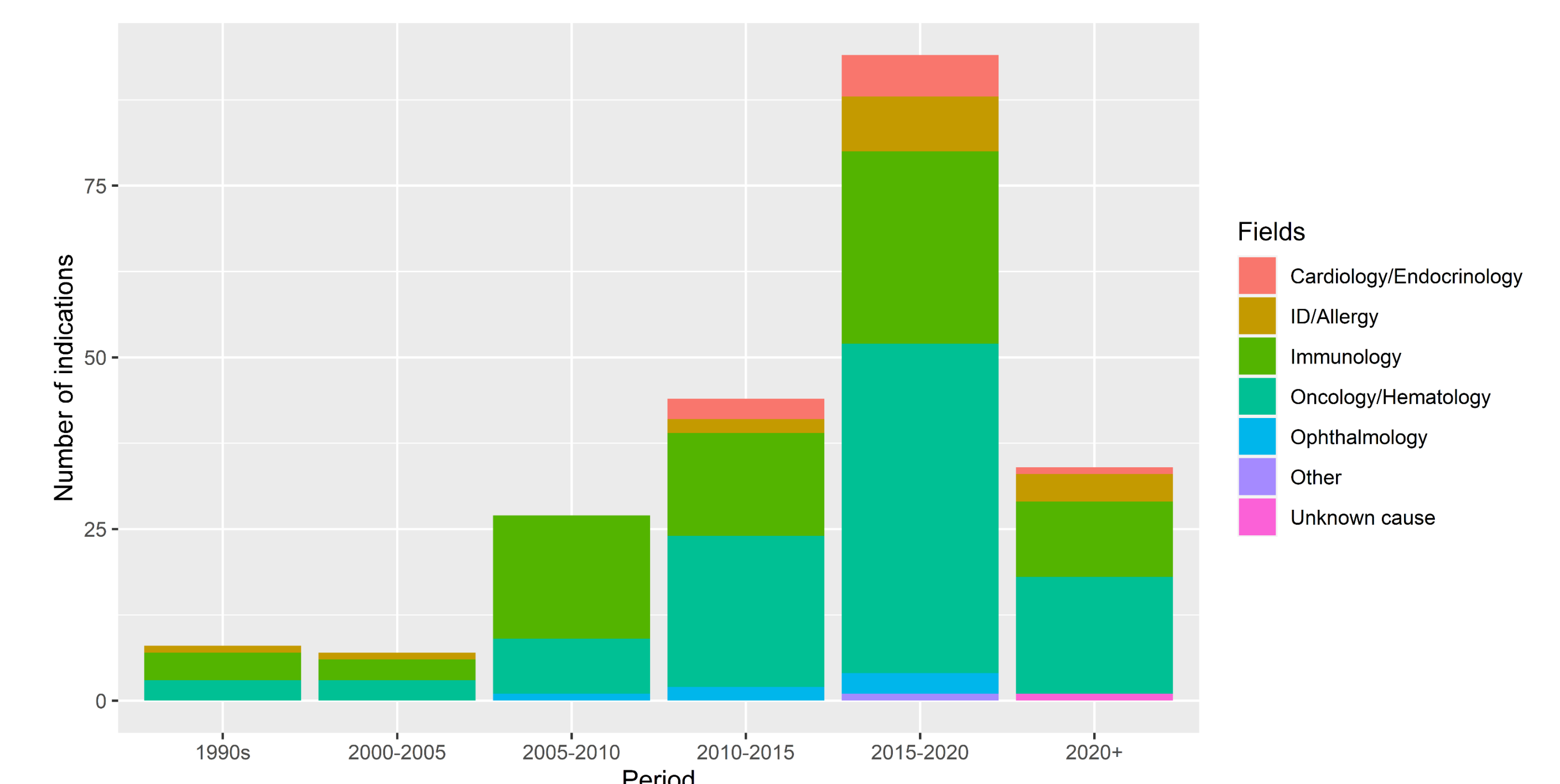
Figure 3. Progression of patent and priorities for mAbs and chemical drugs.



From this point forward, the number of patents associated with mAbs and their priorities started growing.

214 indications were identified. About 36.5% of the mAbs had only one indication in the period. The average number of secondary indications was 3.775 (SD=3.293). **Figure 4** shows the evolution of the indications of mAbs over time. It is possible to observe that the number of mAb indications increased over time and became more diverse.

Figure 4. Indication fields of the mAbs over time.



CONCLUSION

Cancer and autoimmune diseases remain the most common indications for mAbs. Most mAbs have multiple uses, and their indication has become more diverse. The market of mAbs has been dominated by the same companies over the last decades.

Support:

