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THE MARKET FOR MONOCLONAL ANTIBODIES:

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Trends, challenges, and opportunities

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BACKGROUND

Pharmaceutical companies have continuously evolved over the past two centuries in response to exogenous shocks and the need to balance the interests of various interacting agents, such as consumers, profit-seeking firms, regulatory agencies, universities, politicians, and government-funded research centers. Compared to other industries, pharmaceutical companies invest heavily in research and development (R&D) and set high prices for their inventions. Amongst these high-cost revolutionary technologies are monoclonal antibodies (mAbs). This article contributes to the literature by characterizing the landscape of the mAb market through an analysis of patent activity and market data.

METHODS

A dedicated dataset was constructed by linking multiple sources (Antibody Society, Orange Book, Ark Patent Intelligence, USPTO, PATSTAT, Purple Book, US Veterans Affairs, US-FDA, and ORBIS). Data analysis comprised six components: (i) a general description of the dataset, (ii) an examination of mAb patents and approval trends, (iii) an analysis of therapeutic indications, (iv) a characterization of patent holders and producers through descriptive and network analyses, (v) an assessment of shareholder influence, including common-ownership patterns, and (vi) an evaluation of mAb prices.

RESULTS

The dataset included 63 mAbs, 1,732 unique patents, 89 active pharmaceutical ingredients, 34 producers, and 214 therapeutic indications. 36.5% were single-indication while the average number of secondary indications was 3.78 (Figure 1). The number of mAb indications increased over time and became more diverse. About 36.5% of the sample had only one indication at the moment of data collection. The average number of secondary indications for molecules with more than one indication was 3.78 (s=3.29), varying from 1 (various) to 17 (pembrolizumab) (Figure 2).

Figure 1. Progression of patent and priorities for mAbs.

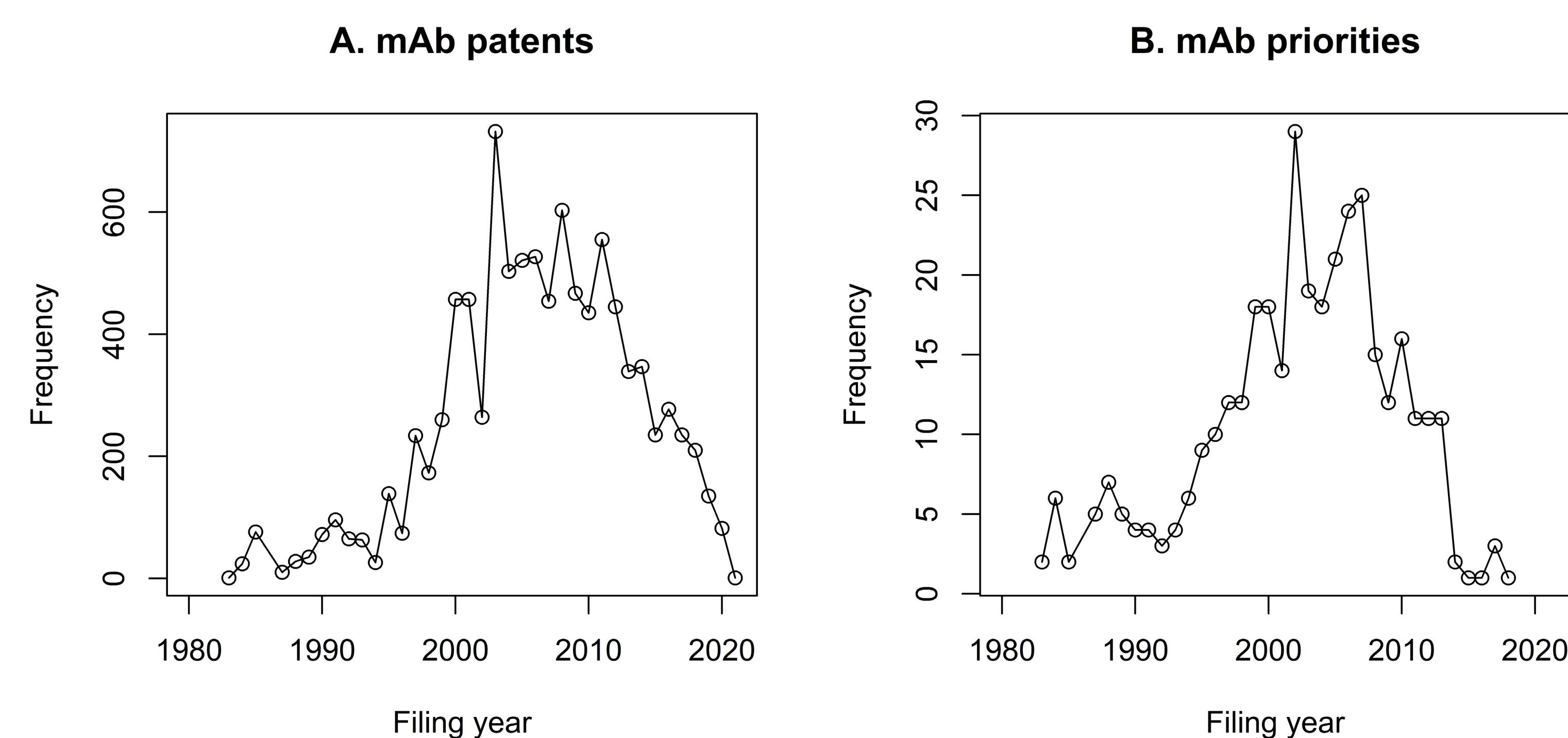
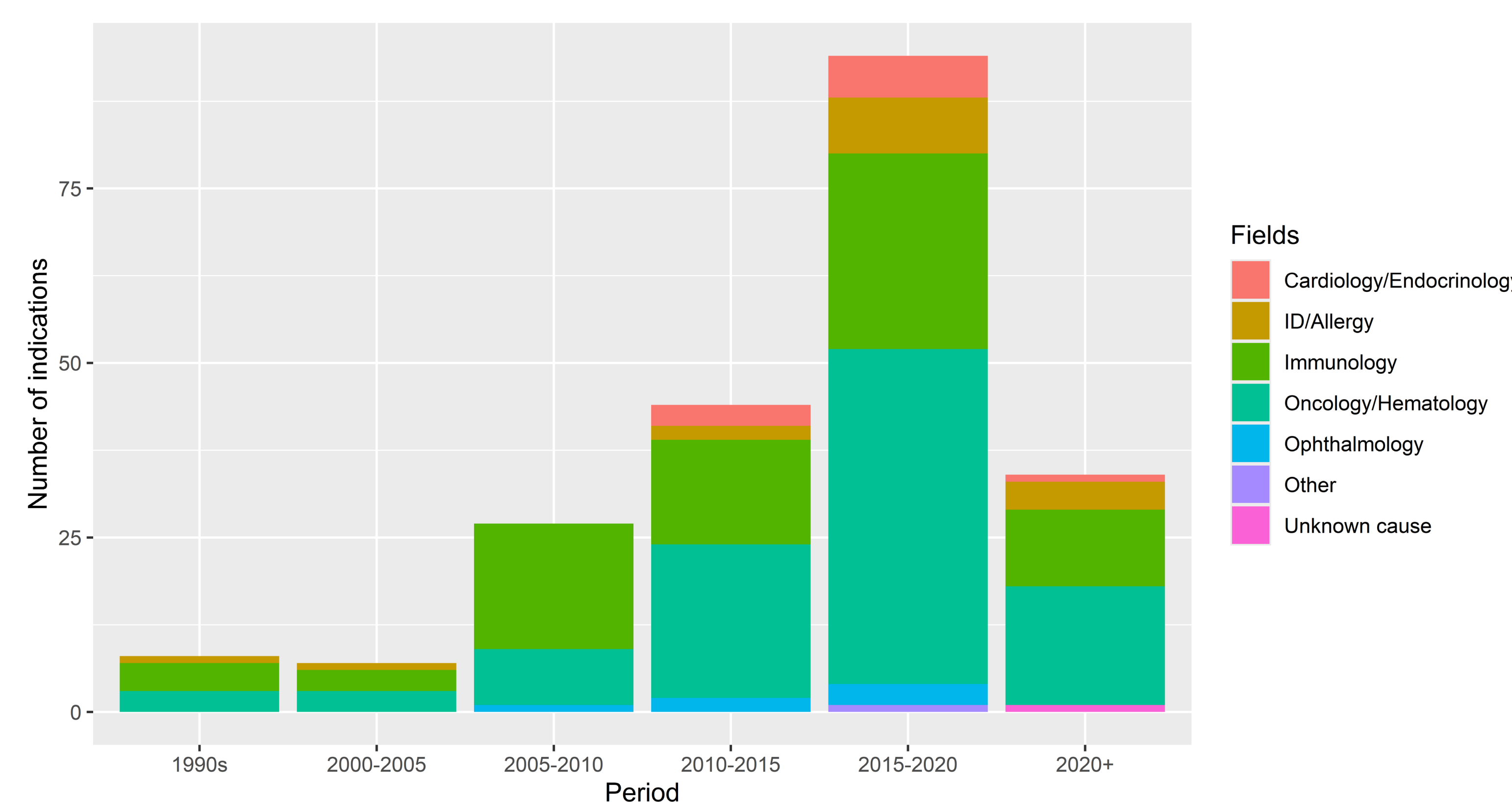
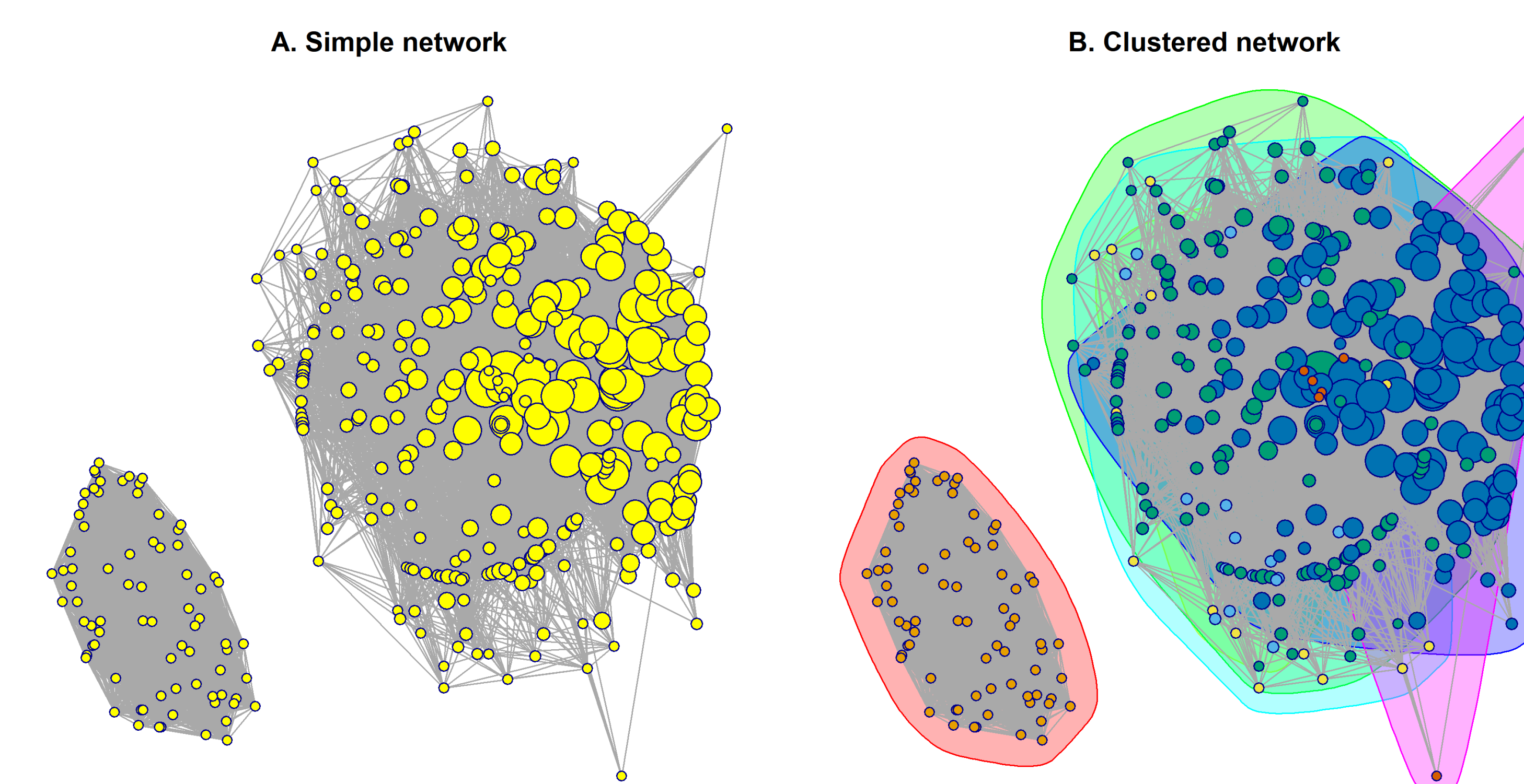


Figure 2. Indication fields of the mAbs over time.



The most central firms in the network analysis included Amgen, Roche, Pfizer, Celltrion, and Samsung, with shareholders such as BlackRock, UBS, the Vanguard Group, and JPMorgan Chase exerting strong market influence (Figure 3). Prices were extremely high, averaging US\$127,430 per course or year (s=US\$142,509), with 42.1% of mAbs priced above US\$100,000. mAbs were approximately 250 more expensive than gold. Patent thickening and evergreening are relevant problems in this market, contributing to its concentration.

Figure 3. Network analysis of producers and molecules.



CONCLUSIONS

Monoclonal antibodies (mAbs) have transformed modern medicine, offering unprecedented therapeutic advances across a growing range of diseases. Their clinical impact is undeniable, with significant gains in safety and effectiveness; however, their persistently high prices raise serious concerns about equity and social welfare. Our analysis shows that mAb prices are objectively high. Moreover, drug prices appear to be shaped by multiple factors, including disease severity, rarity, availability of alternative treatments, presence of biosimilars on the market, level of innovation (reference drug or biosimilar), package size, administration technology (e.g., prefilled syringes, vials, pens), demand, production scale, market power and concentration, and common ownership.

SUPPORT

