From an economic perspective, originators in such a disentangled model benefit from a lower risk profile, which however comes at the price of greater complexity, transaction costs and a higher dependency on the economic bargaining function of the patent system for striking effective licensing deals.[279] If more rather than less deal-making behavior will be required to bring an innovative drug on the market, patent thickets and blocking patents are likely to become an integral part of business strategies. It may also naturally bring the need for greater attention towards restrictive agreements according to Art. 101 TFEU.

Determining the abuse of a dominant position under Art. 102 TFEU in such a disentanglement scenario may also be affected: Originators may lose important arguments as large profits generated by patent exclusivities would be even less correlated with expected benefits from future R&D investments, as those are then made by different entities. In other words: As originators detach themselves from early stage research risk, they are also more vulnerable to competition law accusations related to market foreclosure via generic defense practices. A look to the US may even bring up similar discussions as seen in the post *eBay* antitrust decision,[280] where a patent holder not practicing the invention (itself) may not even be granted a permanent injunction against an infringer anymore.

5.1.2. Product Portfolio Shift Towards 'Nichebuster'

In addition to the separation of business activities one can observe originators shifting away from diseases with a large homogenous prevalence ('blockbusters') more towards niche market products and specialty pharmaceuticals ('nichebusters'). Although such segments have much smaller patient populations, competitive pressure from substitutability is consequentially also lower. Originators have acknowledged that even small patient pools can be economically attractive through high prices and reimbursement rates as well as faster, more effective development and approval procedures. Being able to bring a first-in-class therapy on the market is therefore more likely and creating a portfolio of therapies can help to spread

279 See supra note 10 at p. 99 (acknowledging the bargaining function of the patent system).

280 See eBay Inc. and Half.com v. MercExchange L.L.C., 74 U.S.L.W. 4248 (2006).

the costs of promotion.[281] Good examples are rare and orphan diseases, which do enjoy special exclusivity (see chapter 2.1.2).

On the one hand, this trend is the result of a significant evolution in underlying scientific methods, where molecular biology and biochemistry have replaced traditional chemical science turning outputs towards a more 'personalized medicine' approach.[282] High-prevalence disease areas have either been largely exploited (e.g. antibiotics), have become extremely competitive (e.g. most of oncology) or scientific and technical hurdles have been prohibitive so far (e.g. neurodegeneration). On the other hand, this effect can also be regarded as a proactive generic defense strategy: Not only dynamic competition for innovation may be lower in such smaller and specialized markets, but also static competition. The smaller a market is, the lesser profits can be generated by a generic product, while generic development and commercialization costs remain largely unchanged (see drivers of generic entry discussed in chapter 3.3.1.). Consequently, although originator products in these new niche segments may not be totally unattractive for a generic competitor, they will however certainly enjoy a lower priority in market entry vis-à-vis large blockbuster products reaching their LOE.

Although the scientific developments, which have led to such trends, can be very closely associated with antibodies, genetic engineering and other biotechnological advancements, the sector inquiry admittedly neglected the issue of originator's defense against the so called biosimilars or biogenerics, i.e. imitations of such biotechnologically produced drugs.[283] Indeed, it is hard to predict implications as those product markets are still less established and immature. The majority of innovative biopharmaceuticals has not yet lost exclusivity. Today, less than 20 biosimilars are authorized for marketing in Europe. Nevertheless, considering the importance of this segment in the future as well as originator company's efforts to move away from the 'blockbuster' business model,[284] potential limitations for defense strategies should be understood in advance.[285] Unfortunately, many questions remain unanswered today, starting with fundamental issues such as

281 See Simon Goodall et al., Capitalizing on the Crisis – New Ways to Create Value in Biopharma 3, BCG Focus (The Boston Consulting Group 2009).
282 See supra note 10 at p. 471 (announcing to react with the 'EU pharmaceutical framework for the 21st century').
283 See supra note 10 at p. 24.
284 See supra note 78 at pp. 4-5.
285 See supra note 10 at p.24 & p.28 & p.34.

how the relevant market would be defined to determine market dominance of a biopharmaceutical originator in competition with biogenerics.[286]

5.2. Broader Business Models: Scaling and Convergence

As an alternative to more focus, some players pursue transformations which rather broaden their activities:

5.2.1. Horizontal Scalability

Predominantly US-based originator companies, such as *Pfizer*, have continued to strengthen their fully integrated business models through large acquisitions of comparable firms (see chapter 3.1.2). Strengthening customer relationships, reinforcing product brands and continuing to set sights on blockbuster drugs targeting the primary-care segment can be regarded as a 'volume player' model: An attempt to continue the traditional approach with a larger scale and improved capabilities rather than a business model shift.[287]

In the competing generic segment, similarities can be observed: Recent tenders by hospitals and rebate negotiations of big health insurance companies have made generics' profit margins shrink further: In Germany for example, sometimes up to approximately 50 generic companies compete for the same molecule in one tender bid.[288] As a consequence, major generic players, such as Israel's *Teva Pharmaceuticals,* have begun to aggressively grow their business via acquisitions to benefit from the advantages of critical mass, such as increased bargaining power vis-à-vis large customer groups as well as cost degression in manufacturing and logistics. This has led to a substantial consolidation of the segment: While the global market

286 The AstraZeneca approach in defining the relevant market relied on the ATC structure, which is obviously not possible for large biological molecules.

287 Compare supra note 281 at p. 3 with supra note 10 at p.35. The sector inquiry regards those acquisitions as a move towards biotechnology, whereas the acquired targets have mainly been similar traditional originator companies with some focus on biopharmaceutical R&D pipelines, as can be seen based on the announced efficiency gains through synergies.

288 See supra note 78 at p. 5.