5. Implications of Business Model Transformations

The EU Commission's findings of the sector inquiry constitute – as presented – historic observations and thus are mainly based on the traditional 'divide' of business models (see chapters 3.1.2. and 3.1.3.): On the one side large and vertically integrated multinational originators deliver chemical blockbuster drugs, while on the other side small incumbent generic companies challenge these big players post LOE by introducing similar products at much lower costs. It has been largely ignored by the sector inquiry that these clear boundaries and roles are subject to significant change as companies adapt their business models in Europe's dynamic and highly competitive pharmaceutical sector. Competition law will thus be confronted with more complex scenarios. Determining implications on IP related generic defense strategies therefore requires the consideration of these business model transformations.

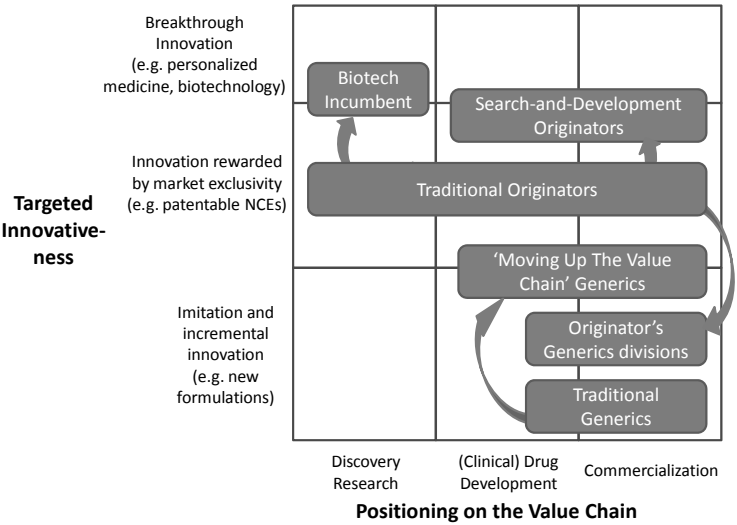

Figure 5:
Pharmaceutical business model transformations according to value chain positioning and targeted innovativeness.[275]

275 Own illustration.

Originators as well as generics have found different strategic pathways to maintain or improve competitiveness in the marketplace:[276] While some apply a more focused approach, others substantially expand their business scope, either in scale or also in substance. Business models can thereby be differentiated according to the model's targeted innovativeness on the one hand and its position within the pharmaceutical value chain on the other hand, which is illustrated in figure 5. The two principle trends leading to those developments as well as their potential implications on generic defense strategies' limitations are discussed in the following chapters.

5.1. More Focused Business Models

5.1.1. Disentanglement of the Value Chain

Some originators, such as e.g. *Shire*, have established so called 'search and development' business models in which preclinical / early-stage discovery research is no longer performed in-house. Instead, attractive drug candidates are in-licensed from smaller research-focused companies, which look for partners to develop and commercialize their products. The source of innovation and thus its associated risk is 'disentangled' and shifted more towards those smaller entities. While those research companies focus on advanced science to provide the breakthrough innovation for successful future drugs, some multinational originators restrict themselves to bringing those candidates through clinical trials and develop marketable products. In the US, this development has already – since the beginning of this millennium – started to fragment the industry into such a two-tier system.[277] In extreme cases, originators even go one step further and not only externally source compounds, but also commercialize finished products via partners (e.g. contract sales forces) instead of using own resources.[278]

276 These observations are largely based on the author's own experience as a strategy consultant for the pharmaceutical industry.

277 See John P. Walsh et al., Research Tool Patenting and Licensing and Biomedical Innovation, in Patents in the Knowledge-Based Society 285 (Wesley M. Cohen and Stephen A. Merrill eds., National Academic Press 2003).

278 As an example, consider the Danish originator Nycomed prior to its acquisition of the pharmaceutical division of Germany's Altana: In this model, Nycomed restricted its in-house operations solely to drug development and 'virtualized' all other steps in the value chain through strategic partnerships.

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).