share of the four leading generic companies was approximately 35% in 1997, it increased to over 60% ten years later.[289]

The strong growth of individual generic players may – in extreme cases – lead to a reverse scenario in terms of scale and market dominance: While a fragmented number of small research-focused entities develop innovation, large multinational generic powerhouses commercially exploit established products. Under such a situation, an originator's market dominance according to Art. 102 TFEU may be more difficult to satisfy, which would allow greater freedom to maneuver in the marketplace. In contrast, some of the discussed generic defense practices may fire back at originators in such a scenario: As building, clearing and litigating patent portfolios cost substantial money and resources, large generic players may in the future be in the powerful position to use similar weapons against smaller research-driven firms.

5.2.2. Business Model Convergence

An originator growing in scale may maintain its traditional business model as discussed above, but may also modify it by participating in the generic segment itself. Companies such as e.g. *Sanofi-Aventis*, have substantially invested into building own global generic divisions to participate in the attractive future growth rates of that business, while accepting a dilution of their ROIC. Moreover, access to and penetration of attractive emerging markets many be facilitated by lower-priced generic products.[290] Already in 2007, originator *Novartis'* own generic division *Sandoz* was the second largest global seller of generic pharmaceuticals with over 7 billion US$ in revenues.[291] Future acquisitions of generics by originators may therefore become a tough challenge for EU competition law's merger control.[292]

Also originator companies without own dedicated generic divisions often rely more on the profit contribution of established products than in the past.

289 See supra note 105.

290 See supra note 10 at p.34 as well as Hanspeter Spek, Executive Vice President Pharmaceutical Operations, Sanofi-Aventis, Presentation at the Pharmaceuticals Emerging Markets Conference (May 6, 2009).

291 See Andreas Rummelt, Chief Executive Officer, Sandoz, Presentation at the Merrill Lynch Generics Conference: Expanding the Boundaries of Generics (Dec. 1, 2008).

292 See supra note 182.

While originators historically have frequently taken products off the market post LOE in order to focus attention on R&D efforts, the absence of R&D success and innovation has forced many companies to continue their commercialization in direct competition with generics.

While originators thus increasingly turn towards established and/or generic products to improve their risk/return ratio, the generic segment is characterized by an opposite trend: Some generic players have begun to put substantial efforts into 'moving up the value chain': They invest into own R&D operations to come up with (incremental) product innovations or substantial improvements themselves. Already in the period covered by the sector inquiry, generic companies invested on average 7% of their revenues into R&D and substantially increased their filing of secondary patents.[293] Own innovation and R&D investments are going to become especially relevant in the area of 'biosimilars', as biopharmaceuticals can only be successfully 'imitated' with much more effort and understanding of the underlying biological science of those large molecules: The German association of generic industries estimates average development costs per biosimilar of more than 200 million €.

When generic companies move from imitation towards innovation, originator companies need greater care in applying IP related generic defense strategies: The delay of market entry of a generic product which has more to offer than just lower prices may be regarded as prohibiting not only static but also dynamic competition in an abusive manner according to Art. 102 TFEU: If a generic product competes convincingly over safety or efficacy advantages, effects on the marketplace may be regarded as a matter of access to medical innovation. Competition authorities may thus have more arguments in finding anticompetitive effects from delay tactics, which will however depend on how broadly they will define 'innovation'.

293 See supra note 10 at p. 40 & p. 180.