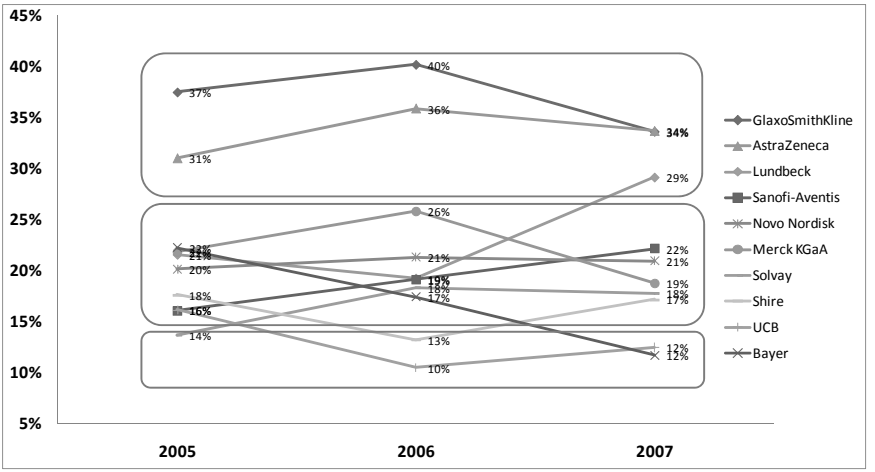

Figure 3:
ROIC 2005-2007 of publicly listed European originator companies amongst the Global Top-50[97]

3.1.3. Generic Pharmaceutical Companies

Besides the traditional originators, generic companies have emerged, which pursue a substantially different business model: Their objective is to 'imitate' established or mature products, i.e. drugs which have already been marketed by originator companies over a long period of time and have or will be soon subject to LOE.[98] Thereby, generic companies 'take over' the (manufacturing and) commercialization of such products in the most cost efficient way and thus ensure certain stability in supplying these products to patients.[99]

In contrast to counterfeits, which are illegal copies not subject to any quality control,[100] generic pharmaceuticals are legitimate copies subject to rigid regulatory approval processes. By proving bioequivalence vis-à-vis the originator's reference drug, generics are allowed to rely on the clinical

97 Data provided by Accenture Management Consulting research; invested capital used to compute ROIC does not consider capitalized goodwill; company selection based on supra note 91 at pp. 70-78 (only publicly listed companies considered).
98 See supra note 1.
99 See supra note 78 at p. 4.
100 On this confusion, see Kevin Outterson, Counterfeit drugs: the good, the bad and the ugly, 16 Alb. L.J. Sci. & Tech. 526 (2006).

safety and efficacy data produced in course of the marketing authorization process.[101] R&D efforts therefore are substantially lower compared to originators, which consequently also leads to a more favorable risk profile and substantially leaner cost structure.[102] As a result, generics need to generate profit levels just over marginal costs of bringing the generic drug on the market. These need to be sufficient to finance investments into e.g. manufacturing and supply chain capabilities, as the ultimate objective is to optimize operations and use scale efficiencies to minimize the costs of goods sold (COGS). In line with the lower risk involved, expected shareholder returns are therefore also lower compared to investments in originator companies.

In comparing cost structures, the sector inquiry emphasizes the substantially higher costs for marketing and sales of originator companies. Without explicitly saying so, the final report appears to link these additional marketing costs to allegedly more aggressive commercial behavior of originator companies in the marketplace. The EU Commission seems to suspect that the performance of some originator companies would be based on marketing tactics rather than innovation, constructing a conflict between investments into R&D and marketing and sales.

A more differentiated view would however rather argue that generic companies do not have lower marketing and sales costs because they are less aggressive in the marketplace. As generics sell over price rather than innovation, they simply cannot afford higher marketing costs in order to be able to compete against each other. From the originator's perspective, R&D investments often trigger or correlate with marketing and sales investments: Innovative products are scientifically complex and novel and thus require substantial efforts to explain to physicians the area of application, therapeutic effects and potential issues e.g. related to multi-morbidity. One should thus keep in mind, that generic products therefore partially not only 'free ride' on originator's R&D investments by imitating established science, but also on originator's commercial efforts, as established products sell much easier than newly launched innovative products.

In 2007, the generic segment represented approximately 18% of the value of EU's human prescription drug market worth approximately 22 billion

101 See supra note 10 at pp. 39-40.
102 See Id.

EUR on an ex-factory basis.[103] Interestingly, only one European generic company, i.e. Germany's *Ratiopharm*, is represented within the Top-50 pharmaceutical companies. Beyond this, only four other non-EU generic companies appear on the list, i.e. *Teva*, *Mylan*, *Watson* and *Actavis*. Except for *Teva*, all of them generate global annual sales significantly below 5 billion US$. This confirms the sector inquiry's finding of generic companies being generally smaller and more localized compared to originators.[104] One should however not forget that approximately 40% of the total worldwide generic sales in 2007 was generated by two market leaders: Israel's *Teva* as well as *Sandoz,* originator *Novartis'* own generics division.[105]

3.2. Dimensions of Competition

Originator and generic companies compete within Europe's common market. However, available legal protection instruments for innovative drugs as outlined in chapter 2.1.2 require a more differentiated consideration of existing competitive forces in order to effectively analyze the sector inquiry's findings.[106] Before the discussion turns towards potential limitations of generic defense strategies, this chapter therefore discusses the difficulties involved with dynamic competition on the one and static competition on the other hand.

3.2.1. Dynamic Competition for Substitution by Innovation

Dynamic competition is what the traditional originator business model is all about: Different market participants compete for product substitution by inventions, not by imitation of the same invention. Originator business strategies therefore 'race for innovation' to launch a first-in-class patent protected product with effectively no substitutability ('first to discover, first to patent').[107] *Etro* calls this a 'winner-takes-all' race. In contrast, patent

103 See supra note 11 at p. 59.
104 See supra note 91 at pp. 70-78 as well as supra note 10 at p. 37.
105 See Eyal Desheh, Chief Financial Officer, Teva Pharmaceuticals and Bill Marth, President and Chief Executive Officer, Teva North America, Presentation at the 27th annual JP Morgan Healthcare Conference: Introducing the World Leader in Generic Pharmaceuticals (Jan. 12, 2009).
106 See supra note 10 at p. 25.
107 See Id. at p.25 and 379.