vention and incremental inventions.[114] As *Schnelle* argues, EU competition law may however consider practices of dominant IP right holders abusive where they have a substantial limiting effect on dynamic competition for innovation. Such competition, which is based on specific techniques, technologies or standards, thus is also safeguarded by competition law even against exclusive IP rights.[115] As *Drexl* puts it: *"'Successful' innovation is allowed, and is even expected, to override inferior technology and to win market dominance. However, such dominant positions in a competition-oriented IP system should remain contestable."*[116]

The boundaries of such cases obviously depend on the underlying definition of pharmaceutical product innovation. This general issue is indeed substantially more complex for drugs than for other goods, as some drugs may not be able to achieve patent protection, but still provide incremental therapeutic improvements, which is a classical line of argumentation by generic companies.

3.2.2. Static Competition for Imitation of In-Market Products

In contrast to dynamic competition, static competition optimizes the allocative efficiency of resources at a certain point in time by driving down prices to marginal costs. Although this is what theoretically happens at a drug's LOE, in reality, a certain minimum level of static inefficiency is system-immanent. The reason lies in the European public healthcare system being built around the principle of solidarity. This system is faced by a typical principal-agent dilemma: While physicians and patients decide about a specific therapy, associated costs are borne by others, i.e. the health insurance.[117] The health insurance as the principal thus is unable to control the necessity of drug prescription and consumption by the agents, i.e. physi-

114 This is because a refusal to license an invention to a dependent patent holder generally is legitimate (however with exceptions as outlined in chapter 4.2.1.); see supra note 59 at pp. 43-44.

115 See supra note 41 at p. 169.

116 Josef Drexl, Responding to the Challenges for Development with a Competition-Oriented Approach, in 1 International Centre for Trade and Sustainable Development, Views on the Future of the Intellectual Property System 17, 19 (John H. Barton et al. eds., 2007).

117 See supra note 68 at p. 17 and supra note 10 at p. 28 and p. 46.

cian and patient.[118] What follows is a problem of moral hazard, whereby drug prescription is suboptimally high as the responsible parties have no clear interest to behave more efficiently.[119]

The effects of static competition at LOE need to be considered in light of the characteristics of the information and knowledge necessary to develop an innovative drug: The science associated with the development as well as any clinical trial results can be regarded as public goods: Existing products are normally relatively easy to imitate through reverse engineering – the first mover advantage for a new product would therefore be too short to recoup investments without any IP protection.[120] Consequently, at LOE, generic market entry initiates so called 'hyper-competition' on the price dimension, which is why legislators regard generic companies as the key factor in realizing associated cost reductions for public healthcare systems in EU member states. According to the sector inquiry results, initial price levels for generic products are on average 25% below the originator's reference product (if compared prior to LOE). This level drops even further to an average of 40% two years after the first entry.[121] On the one hand, this is what originator companies frequently call the 'patent cliff' which they need to find ways to sail around in order not to lose substantial revenues and profits. On the other hand, static drug competition has contributed around 3 billion EUR in healthcare cost savings between 2000 and 2007, which underlines the EU Commission's motivation to fight any delayed generic market entry, which would strain healthcare budgets and – ultimately – all tax payers funding this system.[122]

As originators are not interested in competing with generics and therefore sometimes take established products off the market post LOE,[123] one may stress the 'downstream' character of generic companies: Are originators

118 A similar principal-agent problem also exists between physician and patient, see e.g. Richard G. Frank, Behavioral Economics and Health Economics 7 (Yrjo Jahnsson Foundation, 50th Anniversary Conference on Economic Institutions and Behavioral Economics, May 20, 2004).

119 See Udo Schneider, Kostenfalle Gesundheiswesen? Ökonomische Herausforderung und Perspektiven der Gesundheitssicherung 14 (University of Bayreuth, Discussion Paper No. 08-03, 2003).

120 See supra note 13 at p. 42.

121 See supra note 10 at p. 78, § 212.

122 See supra note 14 at p. 432, supra note 28 as well as supra note 10 at p. 373.

123 Those are cases where the remaining profits reduced by price competition are too small to justify the remaining commercialization efforts.

and generics in a vertical rather than a horizontal competitive relationship? While originators invent and develop new drugs, generics improve manufacturing and optimize distribution efficiency, which may be regarded as a different, subsequent type of business. Such an argumentation would allow originators more room to maneuver in applying generic defense strategies before being in conflict with competition law. This is because the prerequisite of market dominance would be harder to satisfy due to a necessarily broader definition of the relevant market. Nevertheless, as already outlined in chapter 2.2.1., the sector inquiry has made clear that the EU Commission wants to build on the *AstraZeneca* case, which had adopted the more traditional horizontal relationship.

In response to the EU sector inquiry, it cannot be overemphasized that an originator's attempt to attenuate static competition should in general be regarded as a legitimate interest:[124] Like in any other industry, the fundamental purpose of modern business strategy is to build, maintain and expand competitive advantages in the marketplace. It is therefore worrying that the sector inquiry, as well as scholars like *Schnelle*, articulate the concern, that the patent system may be used as a 'strategic instrument'.[125] In a work done for the EU Commission, *Harhoff et al.* define the strategic use of the patent system as "*whenever firms leverage complementarities between patents in order to attain a strategic advantage over technological rivals."*[126] As *Harhoff et al.* correctly emphasize, this generally should not provide any guidance for *per se* anticompetitive behavior:[127] Why should a strategic approach to IP generally be more illegitimate than the use of other property rights? Ultimately, the purpose of defending against generics is to damp threats of static competition and generate profits from existing products with the goal to fully focus on the core of an originator's business model: Develop innovative pharmaceuticals in dynamic competition for scientific progress with other originator companies. As this legitimate objective should be generally acknowledged, it feels extraordinarily hard to define the boundary of anticompetitive behavior.

124 See supra note 68 at p. 27.
125 See supra note 41at p. 169.
126 Dietmar Harhoff et al., The strategic use of patents and its implications for enterprise and competition policies 78-80 (final report, Tender for No. ENTR/05/82, Jul. 8 2007.
127 See Id. at p. 79.

3.3. Entry of Generic Competition

LOE and static competition are triggered by generic entry. In order to understand the approach a generic defense strategy needs to take, it is necessary to highlight some aspects on drivers and timing of generic entry.

3.3.1. Key Drivers for Generic Entry

Generic companies predominantly enter market segments with large potential volume sales as profits per product are rather low. Thereby they capitalize on the reference product's market by focusing on the most commonly sold product formulations – on average 2 to 2.5 generic formulations compared to the originator's product variety of 3.5 to 4 formulations. Only subsequently, they enter into line extensions, e.g. develop additional formulations, dosage forms or delivery methods.[128]

From a geographic dimension, generics prioritize EU member states in which generic drug demand is high, e.g. due to a large relevant patient population, low affordability of originator drugs or favorable national healthcare legislation (e.g. through compulsory generic substitution in the pharmacy or non existing generic price caps).[129] The sector inquiry concludes that national healthcare legislation is the single most important driver of market attractiveness for generics.[130] This explains the unevenly distributed generic penetration rate within the EU: While 61% of all pharmaceutical sales in Poland 2007 were generics, penetration in Spain was only 7.2%.[131]

Consequently, overall generic threat and the need for an originator to defend its positions are targeted towards the 'backbone' of an innovator's business: Blockbuster products in the most attractive markets.[132] The sector inquiry has identified cases where such single products are responsible for almost 20% of an originator's global annual sales.[133]

128 See supra note 10 at p. 36 & 69 & 77.
129 See supra note 7 as well as supra note 10 at p. 44 and 61.
130 See supra note 10 at p. 36 and p. 61.
131 See European Federation of Pharmaceutical Industries and Associations (EFPIA), The Pharmaceutical Industry in Figures (2009).
132 See chapter 3.1.2. about the definition and relevance of blockbuster drugs for originator business models.
133 See supra note 10 at p.16, p.27, p.67 and p.69.