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.

3.3.2. Timing of Generic Entry

Stiff price competition within the generic segment itself, which *Porstner* argues has been largely ignored by the sector inquiry, is the main motivator to *inter alia* challenge originators' patents and enter a market as early as possible. Once the attractiveness of a potential generic version of an established product is assessed, generic companies strive for entering the segment as the first one in order to appropriate as much return as possible in an oligopolistic competition against the originator's established product until other generic entrants come in (i.e. 'first mover advantage').[134] In contrast to the US regulatory system, which allows the first generic under special circumstances to benefit from an additional 180-day exclusivity period vis-à-vis other generic market entrants, the 'first mover advantage' in Europe is small: Average generic penetration rates are already 25% in value just one year after first generic entry, which then increase to 38% one year later.[135]

The sector inquiry provides extensive empirical evidence that proves a first generic product – on a weighted average – being available 7.9 months after the LOE of the reference product.[136] The difference between first generic market entry and LOE is defined as 'time to entry'. The EU Commission therefore generally strives for a situation where generics would be available on the first day after LOE and consequently considers the full 7.9 months as 'delay'.[137] This very narrow understanding seems to reflect an ambitious goal, is however line with European patent law, where the Bolar exemption is also supposed to facilitate an early-as-possible transition from market exclusivity towards stiff static price competition after patent expiry (see chapter 2.1.2).[138]

One fact pattern however remains interesting: For the 20 most valuable drugs, generic market entry is 45% faster, i.e. only takes 4.2 months post LOE.[139] As generic companies prioritize their investments to enter a product

134 See supra note 78 at p. 5.
135 See supra note 10 at p. 87.
136 See supra note 14 at p. 432 as well as supra note 78 at p. 7.
137 To what extent a 'day-1' availability for generic drugs would be realistically achievable and how big the lever of improving regulatory procedures really is does not lie within the scope of this thesis.
138 See supra note 59 at pp. 43-44.
139 See supra note 7.