4. Potential Future Limitations for Generic Defense

Originators have developed a broad set of IP-related strategies to defend its mature product portfolio against generic competition. As this thesis cannot devote time to descriptively outline all general practices existing[141] – many of which have and will continue to be legitimate and without legal conflicts – this chapter directly focuses on potential limitations based on the individual issues highlighted by the EU Commission.

Before individual practices are discussed, a framework to assess the potential for limitations of future behavior will be developed. It is mainly built on the problems of proving a cause-effect relationship between certain practices on the one hand and anticompetitive effects on the other hand. Moreover, also the cumulative use of multiple practices should be briefly discussed as an area for further complexities and uncertainty.

4.1. Causalities, the PACE Framework and Cumulative Use of Practices

The statistical evidence presented in the sector inquiry's final report concludes that approx. 1.5 to 2.8 years (or 19-35%) of the total average time to entry would be caused by originator behavior, i.e. generic defense strategies successfully delaying an otherwise much earlier entry (see chapter 3.3.2).[142] This allegation – already after the inquiry's preliminary report was published – has been subject to an intensive controversial debate: While the generic industry regards the contribution of originator's behavior to market entry delays as substantial and underestimated,[143] originator companies have frequently defended themselves by pointing to errors in the sector inquiry's methodology and evaluation results as well as to the neglected delay effects caused by the regulatory framework.[144] Indeed, many

141 For a structured overview of general life cycle and patent expiry strategies see e.g. Pierre Chandon, Innovative Marketing Strategies after Patent Expiry: The Case of GSK's Antibiotic Clamoxyl in France, 4 Int'l J. Med. Mrktg. 65, 65-73 (2004).
142 See supra note 10 at p. 508 and p. 370 § 1059.
143 See supra note 78 at pp. 10-11.
144 See supra note 11 at pp. 57-62.

observers argue that the EU Commission has failed to produce robust statistics for clear causal links. According to *Rosenberg,* it remains unclear whether such an exercise would be too complex to be conducted.[145]

As modern competition law needs to decide about anticompetitive behavior on a case-by-case basis,[146] such general causalities would not be helpful to establish *per se* rules on competition law violations anyway. Therefore, a more pragmatic assessment framework is developed by this thesis to determine the threat to future limitations of individual generic defense strategies. The framework can be summarized under the acronym **PACE** according to its four assessment dimensions **P**riority, **A**bility, **C**hangeability and **E**nforceability:

First, certain behavior is perceived as more critical by the EU Commission than other – sometimes this perception may exist independently from the practice's factual contribution to generic delay. The sector inquiry thus has outlined certain **P**riorities in investigating future anticompetitive behavior.

Secondly, competition law violations of some generic defense practices may be easier to prove and/or monitor by the EU Commission than others. For some practices, a national member state route may provide 'easier' legal remedies, while other practices may practically be shielded due to impossible evidence collection.[147] The sector inquiry thus has indicated EU Commission's **A**bilities as being extremely relevant.

Third, as discussed in chapter 2.2.4, the EU Commission is able and willing to initiate policy change where necessary and appropriate. The sector inquiry thus has indicated the opportunities of **C**hangeability of the doctrinal legal basis.

Fourth and last, as a complement to policy change, the EU Commission has no obligation to investigate every individual case of potential anticompetitive behavior. It rather has discretionary power to initiate individual cases as outlined by the 2009 guidance on the Commission's enforcement priorities.[148] Some individual generic defense strategies are thus more predestinated for **E**nforceability than others.

145 See supra note 11 at p. 69.
146 See the discussion about the 'more economic approach' to competition law in chapter 2.2.3.
147 See supra note 9 at p. 591.
148 See supra note 53.

Unfortunately, the EU Commission has emphasized that a cumulative use of individually legitimate defense practices may exponentiate its defensive and by that also its anticompetitive effects.[149] Although the final report articulates that a cumulative use would not render individually legitimate practices illegal, *Ullrich* stresses that a simultaneous combination of IP acquisition and enforcement practices may become problematic especially in cases where the underlying protective right is weak. Anticompetitive IP practices of a dominant firm may be regarded abusive where – otherwise legitimate actions – intensify a practice's anticompetitive effects.[150]

While keeping the above in mind, an assessment of cumulative actions is – per definition – highly case-by-case specific. The subsequent discussion will therefore focus on better understanding the risk associated with individual IP related generic defense practices according to the PACE framework. The four PACE dimensions will be then later used to summarize the assessment results and focus attention of originator's need for change.

4.2. Impact Assessment of Individual Generic Defense Practices

Six individual issues associated with IP related generic defense strategies are discussed in the sector inquiry's final report. Those may require originators to revisit generic defense strategies in three key areas: Strategies to restrict a generic competitor's freedom to operate, strategies that create deterring effects to enter a market, and finally strategies intended to prolong existing market exclusivities.[151] The discussion will follow this structure according to the strategy's objectives as summarized in figure 4.

149 See supra note 10 at p.374 §§ 1068-1070.

150 See supra note 59 at p. 38 as well as supra note 10 at p. 374.

151 The EU Commission uses terminology, such as 'defensive', 'blocking' or 'secondary' patents as well as patent 'tickets' or 'clusters', which have often been criticized as being pejorative and not defined in patent legislation. As the EU Commission has acknowledged this and confirmed no intent for any negative connotations, this chapter will continue to use these terms in a neutral way for consistency reasons. See EU Commission, supra note 60.