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.

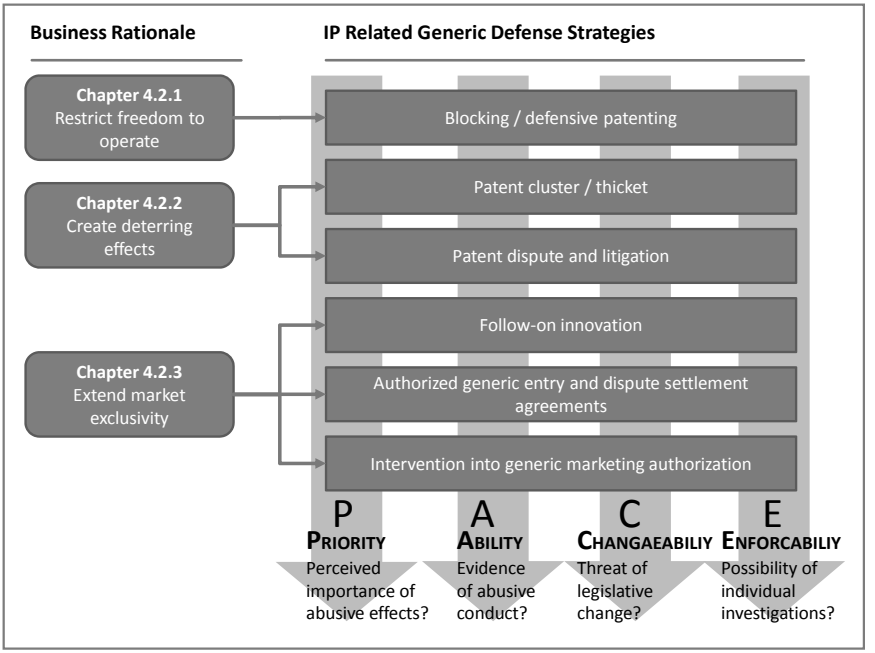

Figure 4:
Structure of analysis - IP related generic defense strategies as addressed by the sector inquiry according to their underlying business rationale and the PACE framework.

4.2.1. Restriction of the Freedom to Operate Through Blocking/Defensive Patenting

The sector inquiry has raised concerns about patentees using their exclusive rights not to economically participate in practicing the underlying invention, but predominantly to block activities of competitors and fence a separately developed invention.[152] This is when the EU Commission speaks of 'blocking patents'. They achieve their effects either directly by prohibiting a competitor to practice, or – more indirectly – by creating new state-of-the-art via a patent (application) and reducing opportunities for others to get patent rights. The term 'defensive patents' is used interchangeably, but also relates to more general situations where a patent is (only) used to

152 See supra note 10 at p. 380 § 1092.

counter a separate legal dispute.[153] Those definitions thus point to the patentee's major intention of restricting a competitor's 'freedom to operate' and secure its own economic situation by protecting an invention's peripheral aspects. They do not point to the features of a patent right itself, as any exclusive right per definition legitimately provides blocking/defensive features.[154]

The EU Commission has raised this topic mainly related to competition amongst originators.[155] Nevertheless, generic delay in principle may also be regarded as an issue: An originator's exclusionary right, which reduces options to develop a generic drug, could lead to market entry delays due to the need to 'invent around' the scope of protection.[156] As science develops and generics become more dependent on specific innovative processes and research tools – such as in the case of biosimilars (see chapter 5.1.2.) – blocking/defensive patents may likely turn even more into the focus of competition law authorities.[157] *Giuri et al.,* on behalf of the EU Commission in 2007, have found that approximately 28% of all patents in the European chemical and pharmaceutical industry could be characterized as blocking patents.[158]

While the sector inquiry has highlighted and refreshed the discussion about blocking/defensive patents, disconcertment had already been felt following the investigation initiated in 2007 against *Boehringer Ingelheim* (BI):[159] In this case, the originator was alleged to have hindered or prevented competitor's market entry by abusing the patent system. BI had applied for various patents related to multiple different combinations of one 'core' substance with different other substances.[160] The sector inquiry provides limited answers and remains vague about when such conduct could be regarded as an abuse of a dominant position under Art. 102 TFEU.

153 See supra note 14 at p. 436.
154 See Id.
155 See supra note 10 at p.381 §§ 1097-1099.
156 See supra note 10 at p. 386.
157 While the Bolar provision (in place since 2005) may provide a solution when experimenting ON a patented invention, it still does not allow experimenting WITH such an invention in the absence of a license agreement. Compare supra note 10 at p. 98, 122-123 and 510.
158 See Paola Giuri et al., Inventors and invention processes in Europe: Results from the PatVal-EU survey, 36(8) Research Policy Elsevier 1107, 1107-1127 (2007).
159 See Case COMP/B2/39246, Boehringer Ingelheim v. Comm'n, 2007 (not yet published).
160 See supra note 65 at p. 94.

It seems clear that the mere submission of an application for one or multiple patents does not impose any competition law limitations. Although such a submission already constitutes a relevant conduct on the market subject to competition law standards, this conduct cannot for itself constitute an abusive effect.[161] Jurisprudence inevitably has – since this doctrine was established in 1966 by the *Consten and Grundig*[162] case – excluded the existence of an IP right from being affected by competition law, while the way these rights are exercised would be governed by it.[163] Moreover, the prerequisite of a dominant position cannot be automatically construed by the patent application itself, but only by the exercise of the patent's blocking function which would show whether there are any substitutes available for the generic firm to not rely on the blocking patent.[164]

When it comes to exercising the blocking/defensive feature of a patent, misuse conduct may indeed be found, such as 'refusal to deal' jurisprudence has shown in the past, as established in the *IMS Health* case.[165] The sector inquiry explicitly refers to the *GSK* case:[166] Herein, the production of an active ingredient was necessary for generics to enter markets. The refusal of *GSK* to license such rights blocked entry also in geographic markets where the originator did not even have patent protection. This behavior was found in violation with Art. 82 EC Treaty (now Art. 102 TFEU). These cases however can be considered exceptions in line with the 'essential facilities doctrine', where narrow conditions need to be fulfilled to render such behavior anticompetitive.[167] A patentee's general freedom to decide to whom he grants a license – even if in a dominant position – has generally been safeguarded so far.

It remains to be seen whether such narrow conditions will be softened in the future. This may potentially lead to also include cases of blocking/de-

161 See supra note 54 at pp. 79-81 (controversially discussing this issue).
162 See Case 56/64 and 58/64, Etablissements Consten SA and Grundig-Verkaufs-GmbH v Comm'n, 1996 E.C.R. 299.
163 See generally supra note 66 at p. 104ff, as well as more specific in supra note 65 at p. 103.
164 See supra note 14 at p. 433.
165 See Case C-418/01, IMS Health GmbH & Co. OHG v. NDC Health GmbH & Co. KG, 2004 E.C.R. I-05039.
166 See supra note 10 at p. 523 (referring to Case A363, Glaxo v. Principi Attivi, 2006, decision of Autorità Garante della Concorrenza e del Mercato).
167 See supra note 65 at p. 102 (quoting those three conditions, which were later also confirmed in the Microsoft decision, see chapter 2.2.2.).

fensive patents, where the patentee has a strong (or sole) anticompetitive intent and does not practice the invention. Although neither investing into R&D nor practicing an invention constitutes a relevant patentability criterion, *Schnelle* argues that originators nevertheless may run into competition law problems where a patent is not associated with any R&D investments. As this may signal such a patent's sole blocking character and purpose, it is therefore advisable for originators to adequately balance financial R&D efforts with the amount of patent filings and offensive litigation in an area of business.[168] The sector inquiry, which seems to be focused on subjective intent as evidence of anticompetitive behavior, therefore may make originators provide specific justification in situations where innovative purposes of a patented invention do not clearly outweigh the patent's blocking purposes.[169] Moreover, it seems that there is a tendency amongst authorities to assess the required dominant market position in such situations not based on the product market of the blocking patent's subject matter, but rather to assume a fictitious patent license market. Such a perspective easily allows presuming market dominance, even if competitive power on the underlying product market is distributed very differently.[170]

Besen et al. speculate that the EU Commission postulates a FRAND-license obligation in such situations.[171] While this would render blocking/defensive patents useless from a generic defense perspective, it would be such a severe intervention into the basic principles of patent law, that it seems rather unlikely.[172] Moreover, as the final report does only provide plausible anecdotal instead of robust statistical evidence, it is unlikely to believe that the EU Commission will be more successful in limiting blocking/defensive patenting than what the failing attempts by German competition authorities had shown already more than 30 years ago.[173] The EU Commission is aware of its limited capabilities and has announced to intensify individual investigations.[174]

168 Compare supra note 65 at p. 98 with supra note 41 at p. 169.
169 See supra note 12 at pp. 30-31.
170 See supra note 41 at p. 169.
171 See supra note 14 at p. 436; FRAND stands for 'fair, reasonable and non-discriminatory terms'.
172 A remaining limitation can be seen in Art. 31 TRIPS, according to which compulsory licenses may be granted for patented inventions with substantial public interest. See supra note 65 at p. 98.
173 Compare supra note 59 at p. 39 (referring to Monopolkommission, Hauptgutachten 1976/77, Baden-Baden 1978).
174 See supra note 10 at § 1571.

4.2.2. Creation of Deterring Effects

As an originator's pharmaceutical innovation – if commercially relevant – opens up new and attractive market segments, it is important for defense strategies to deter generics from entering those markets. Generic defense strategies therefore aim at 'counterbalancing' market attractiveness by signaling '*this market is highly attractive, but entering and exploiting it will come at substantial costs'*.

The sector inquiry's final report has highlighted three areas, where it sees potential cases of foreclosure based on Art. 102 TFEU. As already generally expressed by the EU Commission prior to the sector inquiry, such a *corpus delicti* does not necessarily require forcing a competitor out of the market: Discriminating or disadvantaging competing undertakings is regarded to be sufficient. Cases where a dominant firm directly raises a rival's costs or reduces the demand for a competing product may already constitute a substantial economic disadvantage in conflict with Art. 102 TFEU.[175]

4.2.2.1 Patent Thickets

The sector inquiry suspects 'patent thickets' being built up by originators as market entry barriers against generics. Those thickets protect a 'basic patent' on a newly invented drug compound by additionally surrounding it with all kinds of other patents e.g. on dosage forms, galenic forms or manufacturing processes. Any of those patents are then again multiplied on a geographic dimension into 'patent families' due to the national character of those rights.[176] The resulting portfolio of rights protects different product features in the different EU member state markets of only one single medical product. The top third products with the most annual sales analyzed in the sector inquiry are on average protected by almost 30 patent families, while some products reach around 700-800 individual national patents.[177] *Schnelle* even speaks of approx. 1300 individual patents for a blockbuster product across Europe, which the European Patent Office (EPO) finds to

175 See supra note 65 at p. 101 as well as supra note 56 at p. 585.

176 The need for multiplication into a bundle of separate national patents is a systemic issue of EU patent law rather than of originator's strategic behavior. Normally, one would not count every individual national patent but group them into 'patent families'. See supra note 10 at p. 512.

177 See supra note 10 at pp. 171-172 and p. 188.