6. Conclusion & Managerial Recommendation

Despite all critical voices, originator companies active on the European market should take EU Commission's efforts on pharmaceuticals, as demonstrated by the sector inquiry, seriously. The discussion has shown that competition law scrutiny is likely to increase as the EU Commission has invested substantial efforts in understanding market dynamics, competitive effects and company behavior in the pharmaceutical space. Generic defense strategy after the *AstraZeneca* case can be regarded as an abuse of dominant position even if other legal systems – such as patent law – contain a sanction for misuse (e.g. invalidity) or – more importantly – would render such behavior lawful.[294] Originator companies are therefore well advised to revisit the IP related aspects of their generic defense strategies for Europe prior to execution. Only by that, they can reduce litigation risk and ensure compliance with EU competition law. Such an exercise needs to consider the dynamics and business model transformation trends as outlined in chapter 5.

In contrast to what some authors suggest, it would not be appropriate to only improve the language with which internal IP protocols are recorded to avoid 'careless talk' as a reaction to the EU Commission's demonstrated appetite of using internal company documents as evidence for abusive intent.[295] On the other side, an 'across-the-board' more cautious and conservative IP strategy would also not be an option for originators: This would immediately weaken an originator's competitive position in the highly dynamic European pharmaceutical market. Losing valuable profit opportunities from IP rights does not constitute a sustainable basis to satisfy shareholders' expectations and attract necessary capital to conduct future R&D investments.

Originators should rather apply a differentiated approach in finding priority areas for changing their generic defense strategies. This differentiation should be governed according to the PACE factors, i.e. EU Commission's **p**riorities, **a**bilities, the issue's legislative **c**hangeability and legal **e**nforceability. From the analysis of the sector inquiry's findings, the following

294 See supra note 4.
295 See for all supra note 12 at p. 32.

'step-list' approach is suggested to the management of originator companies:

STEP 1 – Communication and Preparation: Develop a communication approach including consistent arguments for explaining own activities, especially including any diversification in the generic drug segments (if applicable). In general, the more innovative drugs were introduced on the marketplace and the less involvement in commercializing generic products (i.e. a 'pure play' originator) can be demonstrated, the better the basis for justification against alleged anticompetitive behavior.
Internally 'blacklist' generic defense tactics with an obvious sole purpose of excluding rivals, so that only measures are applied which serve additional legitimate purposes beyond delaying or blocking generic entry.

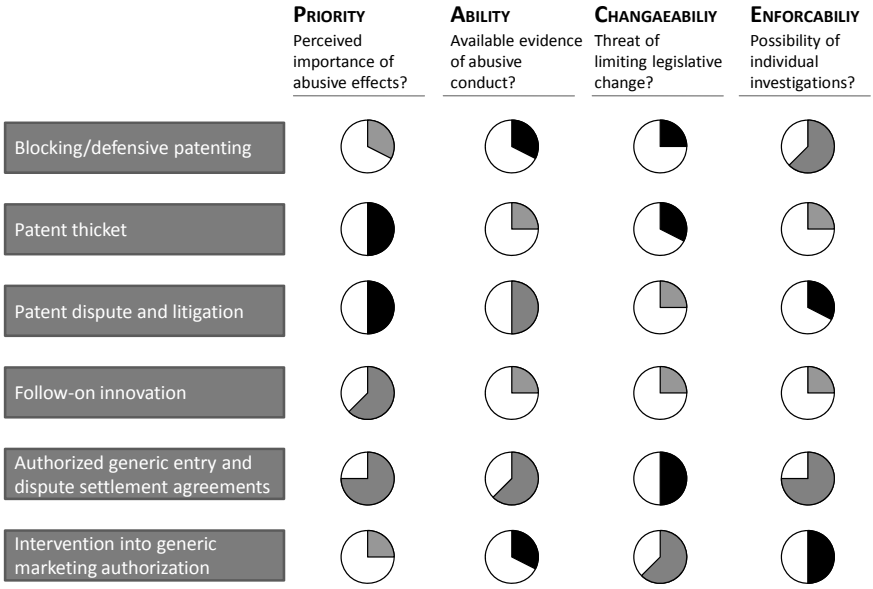
STEP 2 – Market Definition: Review and determine where the firm holds a dominant position by defining the relevant markets according to the methodology established in the *AstraZeneca* case. Get a feeling for the granularity of the legal market definitions based on factors like price and sales elasticity trends as well as usage, demand and prescribing practice to determine potential substitutability.[296]

STEP 3 – Dominant Position: Establish an early warning system to make management aware of the firm's dominant positions. Establish an understanding for 'special obligations' under competition law in those market segments and focus attention to IP related generic defense actions in these areas.

STEP 4 – Generic Product Attributes: Analyze the competing generic product's therapeutic profile to determine any incremental innovative features. Be prepared to present why generic defense does not prohibit dynamic competition and innovative medical progress but only price deterioration necessary to recoup investments.

STEP 5 – Individual Strategy Risk Assessment: Analyze the competition law threat from individual practices based on the PACE factors (see chapter 4.1). Determine the need for behavioral change along the lines of these factors, which is summarized in figure 6, rather than publicly arguing about the factual impact contribution and causality of certain practices on delay of generic market entry.

296 See supra note 4.



Harvey balls indicate relative threat level (greaterfilling = higher treat).
Red color indicate highest relative threat level per evaluation dimension; green color indicate lowest relative threat level per evaluation dimension.

Figure 6:
Assessment results of individual IP related generic defense strategies based on the PACE factors.

5a) Blocking/Defensive Patents: Pay attention to the balance between R&D investments and patent filing. Exercise exclusionary rights of patents that are not licensed or practiced with great care. Be prepared that competition law threats of 'refusal to deal' may be imposed during licensing negotiations.

5b) Patent thickets: Closely monitor systemic change and reforms in European patent law, such as the introduction of the Community Patent, which could further limit opportunities to build thickets.

5c) Patent disputes & litigation: Be aware of the vexatious litigation doctrine and its prerequisites. Carefully follow the introduction of the EPLA proposal, which may change litigation strategies drastically and bring an end to forum shopping.

5d) Follow-On Innovation: Focus efforts of second-generation products on receiving comfortable national pricing and reimbursement while high-

lighting the incremental therapeutic benefits over the first generation product. Link the new product's 'non-obviousness' or 'inventive step' argumentation from patent law to additional therapeutic benefits (i.e. 'how does the incremental invention, which was granted patent protection, help the patient?'). This helps to generate convincing evidence against 'evergreening' allegations.

5e) Authorized Generic Entry and Dispute Settlement Agreements: Be aware of the risk associated with authorities' advantage for proving Art. 101 TFEU compared to Art. 102 TFEU cases and the associated high priority for investigations into this topic by the EU Commission. Try to avoid large monetary value transfers and rather shift towards early entry deals, as they allow an easier basis to argue procompetitive effects and patient benefits.

5f) Interventions into Generic Marketing Authorization: Be aware of the clearly unlawful situation associated with patent-linkage arguments and acknowledge that even trying to intervene may cause competition law consequences in the future. Shift the focus towards intervening via safety and efficacy arguments, which however need to have an objective *bona fide* basis in order to be competition law compliant.

This developed approach is as close as one can get in pinpointing certain limitations and associated pitfalls. Further guidance on the issues raised by the sector inquiry seems to remain remote: A large number of wide-ranging judgments, each of whose final disposition may take years of trial, would be necessary to derive meaningful doctrines given the fact-specific nature of European competition law cases.[297] Furthermore, chapter 5 has demonstrated the dynamic evolution of pharmaceutical business models. Those trends will likely open up new opportunities for generic defense, but will also bear certain additional risk for competition law scrutiny.

It remains to be seen, whether Commissioner *Kroes'* successor in the Competition DG, Spain's *Joaquin Almunia*, is willing and brave enough to build on the sector inquiry's findings. As healthcare budget deficits across many EU member states are not likely to be drastically reduced by national systemic reforms, the EU Commission may feel pressured to actively contribute to a greater focus on static competition over the years to come.

297 See supra note 12 at p. 32.