policy framework as well as on competition law enforcement related to pharmaceutical company's IP practices.[13]

This thesis therefore aims at providing an academic contribution to the lively debate about future limits and implications on generic defense strategies in the European pharmaceutical market based on the sector inquiry's findings. The relevance of this thesis lies in its practical application: With the intention to draw a competition law 'risk profile', it strives to provide valuable guidance to those practitioners who develop tactical measures for defending a pharmaceutical company's competitive position in the marketplace.

As literature has proven that an isolated IP or patent law perspective would only lead to frustrating conclusions about the sector inquiry's identified issues,[14] this thesis thoroughly reflects on the inquiry's implications from a trilateral perspective: IP, economics and competition law. Research objective is thereby to derive a framework for coping with the legal uncertainty related to generic defense strategies today. The results of this thesis should raise innovative pharmaceutical companies' ability to avoid competition law pitfalls and increase the effectiveness of their strategies developed to successfully defend their competitive position.

1.2. Research Methodology and Scope

This thesis focuses on the substantive findings of the sector inquiry's final report and restricts itself to IP related aspects between originator and generic companies on a European level. Similarly to the sector inquiry, also this thesis is limited to the assessment of market entry barriers for human prescription drugs.

Procedural aspects of the sector inquiry are largely ignored as well as any comparative assessment of different jurisprudence or regulatory frameworks on EU member state level. Despite this strict perspective on European law, one should keep in mind that the application of national competition

13 See Christian R. Fackelmann, Patentschutz und ergänzende Schutzinstrumente für Arzneimittel im Spannungsfeld von Wettbewerb und Innovation 2 (Josef Drexl et al. eds., Carl Heymanns Verlag 2009).

14 See, e.g., Marc Besen et al., Zum Kommissionsbericht über die Untersuchung des Arzneimittelsektors – Kritische Notizen aus patent- und kartellrechtlicher Sicht, 9 PharmR 432, 437 (2009) .

laws may in some cases provide a more effective approach for authorities.[15]

Although the sector inquiry also addresses regulatory aspects, the thesis is restricted to implications on individual company strategies and behavior. Consequently, the objective is not to provide normative policy perspectives on the appropriateness of certain EU Commission perspectives.

The thesis is structured into five parts: First, an analysis of the legal and regulatory environment for European pharmaceutical companies, secondly an overview of the European pharmaceutical sector itself, third the analysis of individual IP-related generic defense practices, forth the assessment of pharmaceutical business model transformation trends and, fifth the conclusion and managerial recommendations.

Chapter 2 provides an overview of the governance framework for European pharmaceutical companies. It thereby touches on conflicting healthcare policy objectives being the fundamental source for the high attention the sector has received from the EU Commission. It also describes legal protection opportunities for pharmaceutical products to establish the important concept of loss of exclusivity (LOE). Most importantly, chapter 2.2 analyzes how competition law governs pharmaceutical company's strategies and behavior, which is highly relevant as the intersection between IP and competition law in the pharmaceutical sector is difficult and deserves some attention.

To complement the legal and policy perspective, chapter 3 outlines the business reality of the European pharmaceutical industry. It differentiates business models of originators from those of generic companies and highlights their individual strategic objectives. Moreover, it discusses the different competitive forces in pharmaceuticals, which is critical to understand competition law rationales in prohibiting certain practices.

Chapter 4 then turns towards the analysis of the issues criticized most by the sector inquiry. Before doing so, it devotes some words to the intense discussion about causalities between originator's practices and generic delay as well as to the cumulative use of multiple defense strategies. Before

15 See Council Regulation 1/2003, art. 3, 2003 O.J. (L 1) 1, 8 (setting out procedures to enforce European competition law and allowing stricter standards for determining abuse of a dominant position on a national member state level); similarly, national unfair competition laws may also constitute quick remedies in certain situations.

the six individual IP related generic defense practices are analyzed in detail, the 'PACE' assessment framework is developed.

Chapter 5 outlines industry trends, which will likely lead to substantial transformations of the traditional generic and originator business models. This enables the thesis' findings to articulate hypotheses on what limitations to expect in the future.

Finally, chapter 6 concludes the findings and develops managerial recommendations along a step-list approach applying the PACE framework.