1. Introduction

1.1. Research Objective and Relevance

Pharmaceutical companies involved in developing and commercializing innovative drugs on the European market face turbulent times: Healthcare budget constraints force legislators to apply cost containment measures, which make comfortable drug reimbursement and market access more difficult. Furthermore, many commercially valuable 'blockbuster' drugs are going to reach the end of their exclusivity term, which makes them subject to stiff competition from generic companies. At the same time, science has continuously failed to maintain a level of innovation output, which would be sufficient to fill the widening profit gap. A recent study by *Accenture Management Consulting* expects approximately 40% of the global pharmaceutical industry's product portfolio becoming 'mature' in 2011, i.e. consisting of products where patent protection has either already expired or is about to do so in the coming two years (see figure 1).[1] This demonstrates the increasing importance for so called 'originator' pharmaceutical companies to defend themselves successfully against generic competition.[2]

In this tense situation the case against *AstraZeneca*[3] came in 2005, where it became evident that the EU Commission had started to push the boundaries of competition law to capture certain behavior by pharmaceutical companies. Since then, the industry got aware that *prima facie* adherence to legal or regulatory requirements may not be sufficient anymore to comply with EU competition law.[4] Even more concerning, some authors believe

1 See Andrea Brückner et al., Managing the Profitability of a Mature Product Portfolio: How Intelligent Organizational Approaches, Differentiated Commercial Strategies and Robust Marketing Tactics can drive high-performance in pharmaceutical organizations 4 (Accenture Management Consulting 2010), available at http://www.accenture.com/Countries/Germany/Research_and_Insights/Maturing-Product-Portfolio.htm.

2 Terms are defined further below in chapters 3.1.2 and 3.1.3.

3 Case is currently pending before the European Court of First Instance; See Case T-321/05, AstraZeneca AB and AstraZeneca plc v. Comm'n, 2010 ECJ CELEX LEXIS 62005A0321 (Jul 1, 2010).

4 See Richard Eccles, EU: European General Court upholds findings of abuse of dominant position by AstraZeneca for misusing the SPC and marketing authorising systems (Online News Update, Bird & Bird Jul 28, 2010).

that the *AstraZeneca* case may have paved the way for Intellectual Property (IP) *"protection of medicines [becoming], in some circumstances, […] second to the promotion of competition from generic products which drives down prices."*[5]

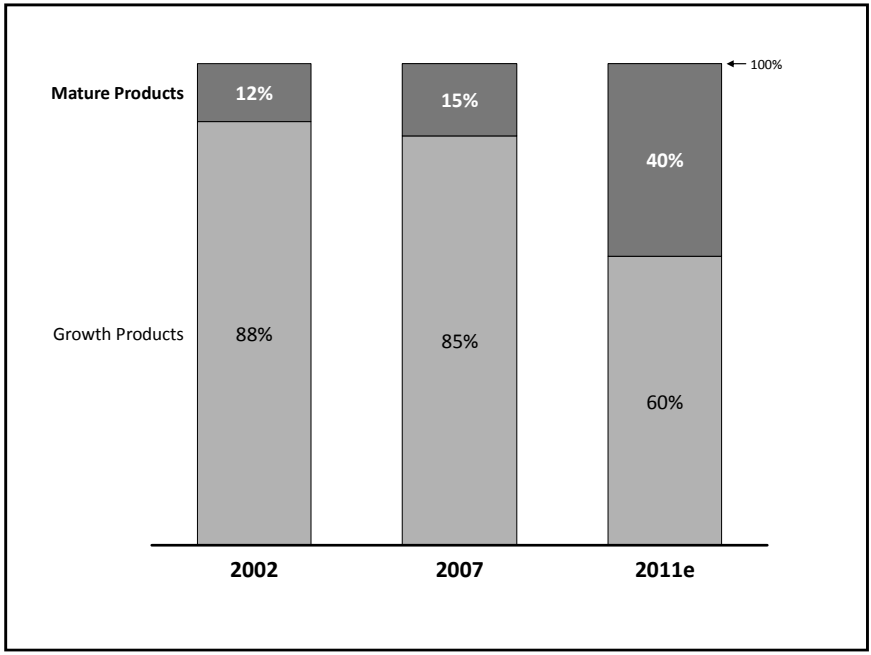

Figure 1:
Proportion of mature products among Top-50 pharma products – expected development over time[6]

In January 2008, the EU Commission started a sector inquiry on the pharmaceutical industry – the first one ever applying unannounced inspections targeted towards many pharmaceutical companies.[7] In explaining the rea-

5 Sophie Lawrance and Pat Treacy Bristows, The Commission's AstraZeneca decision: delaying generic entry is an abuse of a dominant position, 1 Journal of Intellectual Property Law & Practice 7, 9 (2005).
6 See supra note 1.
7 See, e.g., Bill Batchelor and Fiona Carlin, An Analysis of the European Commission's Pharmaceutical Sector Inquiry (Pharmaceuticals, Section 3 EU Industry Sectors, The European Antitrust Review 2010, Global Competition Review), available at http://www.globalcompetitionreview.com/reviews/19/sections/68/chapters/746/pharmaceuticals/.

son for that inquiry, back-then EU Commissioner of Directorate-General (DG) 'Competition', *Neelie Kroes,* remarked that "*if innovative products are not being produced, and cheaper generic alternatives to existing products are in some cases being delayed, then we need to find out why and, if necessary, take action."* The EU Commission also referenced the *AstraZeneca* case as being one of the factors indicating that there may be elements in the market worth of an in-depth investigation.[8]

The sector inquiry's final report was published in July 2009. It raised anti-competitive concerns about multiple business practices, which had not been regarded as relevant to EU competition law or had at least not been the focus of competition authorities before.[9] However, the final report did not provide sufficient explanation under which circumstances these practices would be viewed in conflict with competition law. It consequently attracted criticism from a range of commentators:[10] *Lord Justice Jacob* of the *Court of Appeals of England and Wales* for example found it striking to see the EU Commission's "*immense ignorance of how the patent system works"* combined with the *"high-handedness of the Commission officials starting with unjustified dawn raids and continuing with a reign of terror with a constant succession of questionnaires containing muddle of woolly questions all demanding near instant answers"*.[11]

The public debate has also reflected high uncertainty amongst industry practitioners.[12] This is due to the major influence the sector inquiry's results are expected to have – and already had – on the future EU pharmaceutical

8 See Press Release MEMO/08/20, European Commission, Antitrust – sector inquiry into pharmaceuticals – frequently asked questions (Jan 1, 2008).

9 See Werner Berg and Michael Köbele, Grenzen kartellrechtmäßigen Handelns nach der EU-Untersuchung des Arzneimittelsektors – Risiken und Chancen für betroffene Unternehmen, 12 PharmR 581, 581 (2009).

10 See EU Commission, Competition DG, Pharmaceutical Sector Inquiry Final Report, § 1503-1512 (Jul 8, 2009), available at http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/index.html.

11 David Rosenberg, A view of the research-based industry, in Sektoruntersuchung Pharma der Europäischen Kommission – Kartellrechtliche Disziplinierung des Patentsystems? 51, 64 (Bardehle, Pagenberg, Dost Altenburg, Geissele eds., Carl Heymanns Verlag 2010).

12 See Simon Priddis and Simon Constantine, The Findings and Wider Impact of the EU Pharmaceutical Sector Inquiry, 24 Antitrust 29, 30 (2010).

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) .