MIPLC Studies 11

Marc P. Philipp

Intellectual Property Related Generic Defense Strategies in the European Pharmaceutical Market

Implications of the EU Commission's Sector Inquiry from an IP, Competition Law and Economic Perspective

Nomos

MIPLC Munich Intellectual Property Law Center
Augsburg München Washington DC

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Edited by

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Max Planck Institute for Intellectual Property and Competition Law

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Abstract

This thesis discusses the implications of the 2009 EU Commission's Pharmaceutical Sector Inquiry on originator's opportunities to apply Intellectual Property related measures in defending against generic competition. It argues that on the one hand recent developments in EU competition law do indeed impose potential limitations on an originator's ability to block or delay generic market entry. On the other hand, the thesis calls for a differentiated assessment of the rather broad allegations made by the sector inquiry. The thesis thereby presents and thoroughly analyzes six key issues identified by the EU Commission in the inquiry's final report: Blocking/defensive patenting, patent thickets, patent-related disputes and litigation, follow-on innovation, authorized generic entries and patent settlement agreements as well as interventions into generic marketing authorization. The analysis aims at reducing legal uncertainty by providing a clearer picture of legal boundaries between legitimate and problematic conduct under Arts. 101 and 102 TFEU. An evaluation framework called PACE is developed and serves as the structure for the assessment, which consists of four dimensions, i.e. **P**riority, **A**bility, **C**hangeability and **E**nforceability. The thesis also puts the sector inquiry's findings into a forward-looking perspective by highlighting industry trends with the potential to transform traditional originator and generic business models. Based on a holistic trilateral approach of IP, economics and competition law, the thesis concludes that originator companies are well advised to follow a 5-step approach for revisiting and fine-tuning their IP-related generic defense strategies for the Europe market.

Key words: *Intellectual property, competition law, antitrust, EU Commission, pharmaceutical sector inquiry, generic competition, defense strategies, innovation.*

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Table of Contents

List of Figures 9

1. Introduction 11

1.1. Research Objective and Relevance 11
1.2. Research Methodology and Scope 14

2. Governance Framework of Europe's Pharmaceutical Sector 17

2.1. Policy Objectives and Legal Protection 17
2.1.1. Conflicting Healthcare Policy Objectives 17
2.1.2. Legal Protection of Pharmaceutical Products 19
2.2. EU Competition Law and the Pharma Sector Inquiry 22
2.2.1. Legal Basis and General Art. 102 TFEU Principles 22
2.2.2. The Intersection of IP and Competition Law 25
2.2.3. The 'More Economic Approach' to EU Competition Law 27
2.2.4. The Sector Inquiry as an EU Competition Law Instrument 28

3. Competitive Dynamics in Europe's Pharmaceutical Market 31

3.1. Market Structure and Business Models 31
3.1.1. Market Relevance 31
3.1.2. Originator Pharmaceutical Companies 32
3.1.3. Generic Pharmaceutical Companies 34
3.2. Dimensions of Competition 36
3.2.1. Dynamic Competition for Substitution by Innovation 36
3.2.2. Static Competition for Imitation of In-Market Products 38
3.3. Entry of Generic Competition 41
3.3.1. Key Drivers for Generic Entry 41
3.3.2. Timing of Generic Entry 42

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4. Potential Future Limitations for Generic Defense 44

4.1. Causalities, the PACE Framework and Cumulative Use of Practices 44
4.2. Impact Assessment of Individual Generic Defense Practices 46
4.2.1. Restriction of the Freedom to Operate Through Blocking/Defensive Patenting 47
4.2.2. Creation of Deterring Effects 51
4.2.2.1 Patent Thickets 51
4.2.2.2 Patent-Related Disputes and Litigation 54
4.2.2.3 Implications from Future Patent System Reforms 56
4.2.3. Extension of Exclusivity Terms 58
4.2.3.1 Revitalization through Follow-On Innovation 58
4.2.3.2 Authorized Generic Entry and Dispute Settlement Agreements 61
4.2.3.3 Intervention into Generic Marketing Authorization 68

5. Implications of Business Model Transformations 71

5.1. More Focused Business Models 72
5.1.1. Disentanglement of the Value Chain 72
5.1.2. Product Portfolio Shift Towards 'Nichebuster' 73
5.2. Broader Business Models: Scaling and Convergence 75
5.2.1. Horizontal Scalability 75
5.2.2. Business Model Convergence 76

6. Conclusion & Managerial Recommendation 78

References 83

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List of Figures

1	Proportion of mature products among Top-50 pharma products	6
2	European Pharmaceutical Companies amongst the Global Top-50 Ranking 2008	27
3	ROIC 2005-2007 of publicly listed European originator companies amongst the Global Top-50	29
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	43
5	Pharmaceutical business model transformations according to value chain positioning and targeted innovativeness	72
6	Assessment results of individual IP related generic defense strategies based on the PACE factors	82

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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).

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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]

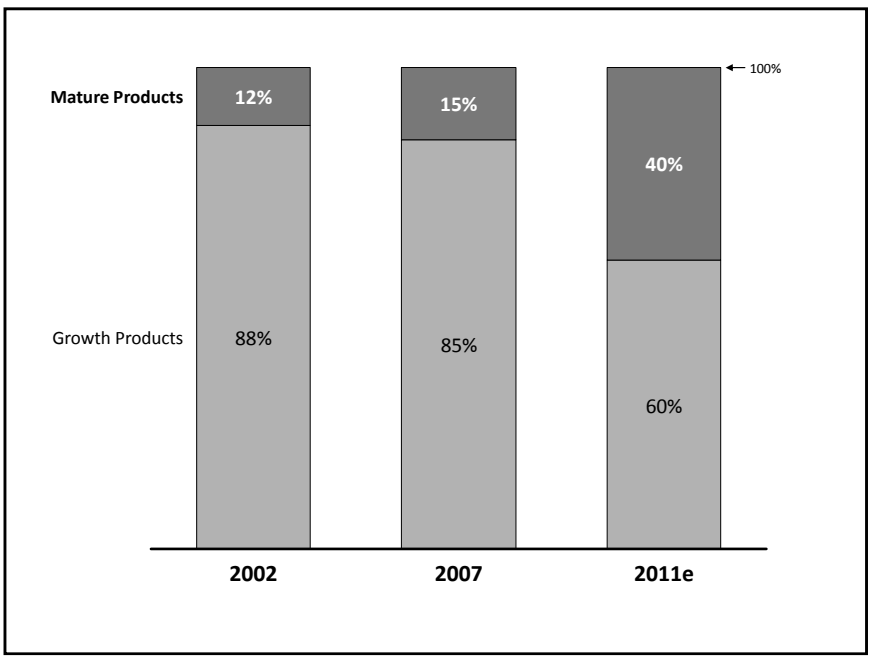

Figure 1:
Proportion of mature products among Top-50 pharma products – expected development over time[6]

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/.

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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).

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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) .

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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.

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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.

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2. Governance Framework of Europe's Pharmaceutical Sector

Europe's pharmaceutical sector is a highly regulated one. On the one hand, undertakings have to adhere to a healthcare policy framework mainly influenced by patient safety and fiscal concerns. They however also benefit from opportunities to legally protect their products from product imitation. On the other hand, the behavior of pharmaceutical companies is governed by competition law. Although competition law doctrines are generally applicable to all industry sectors, they enjoy certain special considerations when applied in the context of the drug industry's characteristics. This chapter discusses important conflicts and opportunities of this governance framework relevant to analyze future implications on generic defense strategies.

2.1. Policy Objectives and Legal Protection

2.1.1. Conflicting Healthcare Policy Objectives

In line with initiatives of national member states,[16] the sector inquiry rearticulates the EU Commission's general policy objective of *"providing European patients with safe, effective and affordable medicines while at the same time creating a business environment that stimulates research, boosts valuable innovation and supports the competitiveness of the industry."*[17]

To promote these policy objectives, the EU Commission runs multiple programs, such as the DG Research's *Innovative Medicines Initiative* (IMI) for granting subsidies for integrated pharmaceutical industry's research activities.[18] Nevertheless, realizing all goals simultaneously represents a great challenge due to two fundamental conflicts:

16 See supra note 10 at p.132 regarding the common goals of the member states.

17 Supra note 10 at p. 10 and p. 478; see also Commission of the European Communities, Safe, Innovative and Accessible Medicines: a Renewed Vision for the Pharmaceutical Sector, COM (2008) 666 final (Dec. 10, 2008).

18 See Satish Sule and Dominik Schnichels, Die Untersuchung des pharmazeutischen Wirtschaftszweigs durch die Kommission, 20 EuZW 129, 129 (2009).

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First, regulatory safety and efficacy requirements come at the price of increased drug development (transaction) costs for pharmaceutical manufacturers. Due to the scientific effort and high uncertainty involved, these costs are already naturally extremely high: Today, the development of an innovative drug from discovery to market can take 10-15 years and costs approximately 450 million US$ to 1 billion US$ - and these investments still not yet eliminate the substantial risk of product liability.[19] Regulatory requirements are thus targeted to protect European patients, but bear the risk of only fewer and/or more expensive products becoming available to these patients – especially in smaller/niche market segments.[20]

Secondly, promoting medical innovation requires incentives to increase the attractiveness for market participants to invest into complex, lengthy, expensive and uncertain research and development (R&D) projects.[21] As *Shapiro* argues, traditional approaches, such as granting IP rights, achieve this by allowing the owner of such a right to appropriate higher returns from its previous investments. This however typically *inter alia* leads to (temporarily) higher drug prices.[22] This conflict is often referred to as the 'innovation vs. access trade-off' or 'innovation dilemma'.[23] The fact that the EU Commission hereby explicitly stresses the promotion of (only) 'valuable' innovation may articulate its skepticism about whether all medical innovations currently rewarded really contribute additional benefits to patients.[24]

19 Compare Thomas C. Caskey, The Drug Development Crisis: Efficiency and Safety, 58 Ann. Rev. Med. 1, 1 (2007) and supra note 10 at p. 55 with Joseph A. DiMasi and Henry G. Grabowski, The Cost of Biopharmaceutical R&D: Is Biotech Different?, 28 Manag. Dec. Econ. 469 (2007) (estimating R&D average investments going even beyond 1 billion US$).

20 Higher transaction costs can lead to drug price increases to maintain profitability. Alternatively, it could also lead to lower profits assuming constant price levels. This bears the risk of drug manufacturing being a less attractive business to pursue. As a result, drug supply, especially in small market segments, may not be profitable, which may lead to lower availability of valuable medicine.

21 See supra note 13 at p. 1.

22 See Carl Shapiro, Antitrust Limits to Patent Settlements, 34 Rand J. Econ. 391, 391 (2003) as well as the in-depth discussion about static and dynamic efficiency in chapter 3.2.

23 See chapter 3.2 as well as William M. Landes and Richard A. Posner, The Economic Structure of Intellectual Property Law 20 (The Belknap Press of Harvard University Press 2003).

24 See supra note 10 at p. 10; as this concern is constantly – often implicitly – repeated throughout the final report of the sector inquiry, this paper addresses this topic thoroughly throughout subsequent chapters, especially in chapter 4.2.3.1.

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At the end of the day, the EU legislator has to conduct a constant balancing exercise for all policy measures, i.e. the consideration of effects on drug quality, availability, price levels as well as the speed and quality of medical innovation. Thereby, a substantial part of the current healthcare system, especially pricing and reimbursement regulation, is not harmonized amongst EU member states and thus remains not under direct control of the EU legislator.

Over the last years, especially the issue of *price levels* and *affordability* has gained greater attention, as overall healthcare costs have substantially increased.[25] No surprise that healthcare spending on human pharmaceuticals is closely monitored, which today represents the third largest healthcare cost component across all OECD countries with disproportionately high growth rates.[26] As confirmed by the sector inquiry, policy priorities in many EU member states have therefore already shifted towards a more rigid regulation of pharmaceutical pricing and reimbursement.[27] Although the EU Commission proclaims that its concerns about the decreasing rate of new drug applications in Europe had been one of their main motivations to initiate the sector inquiry,[28] it seems that their true intention is rather driven by short-term considerations about "*how to lower prices and reduce the strain on national health-care budgets."*[29]

2.1.2. Legal Protection of Pharmaceutical Products

Besides the discussed restrictions derived from general policy concerns, the pharmaceutical industry on the other hand benefits from IP and other sui generis sector-specific exclusivity regimes. Although this being the cause for the above described 'innovation dilemma', pharmaceutical business models having such a heavy R&D burden, would simply not be possible without opportunities for legal protection of exclusivity.

25 Various factors have contributed to an increase in costs, e.g. the demographic development of Europe's population and additional costs per capita due to more costly innovative therapies.
26 See supra note 10 at p.19.
27 For examples see supra note 10 at p.61.
28 See Press Release MEMO/09/321, European Commission, Antitrust: shortcomings in pharmaceutical sector require further action – frequently asked questions (Jul. 8, 2009).
29 Supra note 7.

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Innovative pharmaceutical companies primarily benefit from patent protection. Nevertheless, a complex set of additional pharma-specific exclusivities has been established to close incentive gaps of the patent system.[30] As the protection terms of some of these exclusivity instruments add to each other while others overlap and run in parallel, the concept of 'loss of exclusivity' (LOE) is critical: An innovative drug has reached LOE when the total term, during which the sales of product imitations are legally prohibited, has come to an end. After this date, bioequivalent product imitations may be legally manufactured and sold on the market – typically at substantially lower prices. One can distinguish three different layers of such drug exclusivities:

First, the exclusive rights conferred by patent law provide the basis of legal protection for a drug. As patents provide general incentives across all different technologies and industry sectors, they do not consider the specific characteristics of the pharmaceutical industry. In order to compensate for the time between patent filing and marketing authorization, which can be rather long due to necessary drug development and regulatory approval procedures, Supplementary Protection Certificates (SPCs) may – under certain conditions – complement patent exclusivity terms with additional protection of maximum five years.[31] SPCs therefore link a granted patent right with the independent regulatory regime of pharmaceutical marketing authorization – not without certain inconsistency problems and legally unclear situations.[32]

A major change in the patent regime was introduced by the so called 'Bolar exemption', which has provided much more leeway for the market entry preparation of bioequivalent product imitations.[33] Prior to its introduction, patent protection did not only make the third party manufacturing and sales

30 A full discussion about pharmaceutical protection regimes would go beyond the scope of this thesis. For a general discussion see e.g. supra note 13 at pp.222-283.

31 See Council Regulation 469/2009, 2009 O.J. (L 152); The patent system creates incentives to file an application as early as possible, which means that the point when such a patent is granted may still be many years before the corresponding pharmaceutical product receives marketing authorization and can be effectively launched on the market.

32 See, e.g., Case C-195/09, Synthon BV v. Merz Pharma GmbH & Co. KG, 2009 O.J. (C 193) (pending case as of reference for preliminary ruling from High Court of Justice, England and Wales).

33 The exception allows conducting experimentation on a patented invention, e.g. an originator's drug compound, during the term of protection, in order to prepare for marketing authorization. See Council Directive 2004/27, Art. 10.6, 2004 O.J. (L 136) 34, 40 (EC).

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of a patented drug unlawful without a license, but also drug development experimentation as a mere preparation for fulfilling the abridged generic marketing authorization pathway. This effectively delayed the entry of product imitations beyond LOE of the reference drug. Interestingly, although the Bolar exemption was not in place during the sector inquiry's period of analysis, the final report did not refer to it as one potential source to explain such delays.[34]

Secondly, data exclusivity adds another layer independent from patent law. It serves as a reward for having invested substantially in demonstrating compliance with safety and efficacy requirements via long and complex clinical trials. As generic drugs per definition rely on originators' clinical trial data in the abridged generic approval pathway,[35] data exclusivity effectively blocks their market entry.[36] Although recently changed, data exclusivity did not only prohibit the commercialization of a generic product, but also its mere application for marketing authorization during the sector inquiry's period of analysis. Interestingly, also this fact did not find any recognition in the final report as one potential source of generic delay to market entry.[37]

Thirdly, the first two layers are complemented in specific cases, where the legislator had found it would be worth providing special incentives: Orphan and rare diseases as well as the pediatric use of drugs.[38] These instruments can extend drug's exclusivity on the market – their special and narrowly defined purpose however typically provides only incremental complementary value.

Based on the above, generic defense strategies therefore are defined as the tactics and activities pharmaceutical companies are able to perform to either

34 See supra note 11 at p. 57.
35 See Council Directive 2001/83, Art. 10, 2001 O.J. (L 311) 67, 75 (EC).
36 The so called '8+2+1 formula' is applied: Only eight years after the originator's marketing authorization, generic drugs can apply for marketing authorization themselves, while additional two years have to laps before such authorization is granted by authorities. In case the originator drug was extended to additional therapeutic indications in that first eight years on the market (which obviously constitutes additional effort), the protection is extended by one additional year; see supra note 33 at Art. 10.
37 See supra note 11 at p. 57.
38 See Council Regulation 141/2000, 2000 O. J. (L 18) 1 (EC) for orphan drug exclusivity and Council Regulation 1901/2006, 2006 O. J. (L 378) 1 (EC) for paediatric exclusivity.

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postpone a product's LOE or to attenuate the effect of LOE on profitability.[39]

2.2. EU Competition Law and the Pharma Sector Inquiry

Besides healthcare specific policies and legal protection opportunities, the pharmaceutical sector – like any other industry – is subject to competition law, which is regulated and enforced at both EU and national member state level.[40] The likelihood of any potential limitation on generic defense strategies cannot be determined without a review of the critical doctrines and recent developments in EU competition law jurisprudence, to which this chapter is dedicated.

2.2.1. Legal Basis and General Art. 102 TFEU Principles

As outlined in Art. 3.1 (b) of the Treaty on the Functioning of the European Union (TFEU), competition law prohibits behavior and practices that restrict the functioning of the free internal market environment. More precisely, Art. 101 TFEU bans certain restrictive multilateral business practices, while Art. 102 TFEU makes the abuse of a dominant market position illegal. Cases under Art. 101 TFEU therefore require the involvement of at least two parties in contrast to cases under Art. 102 TFEU, which also apply to unilateral conducts. Very importantly however, Art. 102 TFEU cases require the addressee of the norm having a dominant position on the relevant market before the allegedly abusive practice is conducted.[41] As the application of Art. 101 TFEU generally is regarded to be easier, some words should be devoted to the assessment of Art. 102 TFEU infringements, which the sector inquiry seems to struggle with most:

39 Compare supra note 10 at p. 368, § 1053.

40 As outlined in the introduction, national competition law and policy in member states are outside the scope of this paper.

41 Compare Ulrich Schnelle, Missbrauch einer marktbeherrschenden Stellung durch Patentanmeldungs- und -verwaltungsstrategien, 8 GRUR-Prax 169, 169 (2010) with Dieter Stauder and Pascal Böhner, Bericht über die Diskussion, in Sektoruntersuchung Pharma der Europäischen Kommission – Kartellrechtliche Disziplinierung des Patentsystems? 73, 78 (Bardehle Pagenberg Dost Altenburg Geissler eds., 2010) (contrasting this doctrine to the 'monopolization' doctrine in US antitrust law).

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The current European case law basis for applying Art. 102 TFEU to pharmaceutical companies' practices is small. Nevertheless, the EU Commission has initially addressed generic defense practices explicitly in the case of *AstraZeneca*.[42] Importantly, the decision has established the method to define the relevant pharmaceutical product market,[43] i.e. establishing the basis for any analysis of dominant position:[44] The court used the five-layered Anatomical Therapeutic Chemical Classification System ('ATC classification') by the World Health Organization (WHO) to separate relevant product markets, which is also used by the European Pharmaceutical Market Research Association (EphMRA). In contrast to its application in recent merger cases,[45] the *AstraZeneca* decision has established a narrower definition using the fourth instead of the third layer. This approach thus does not only consider a product's therapeutic indication, but also its mode-of-action.[46] The fact that also the sector inquiry analyzes data on a molecular level indeed indicates certain recognition for pharmaceutical product heterogeneity.

This narrower market definition has consequently lowered the threshold for market dominance.[47] Determining dominance by an undertaking's market share thereby is regarded to be only a rough initial proxy. Instead, dominance is defined by an undertaking's ability to appreciably influence the conditions of competition on the market, which the ECJ has established in its early *Hoffmann-La Roche* decision.[48] The abusiveness of a certain be-

42 See supra note 3; previous investigations in the pharmaceutical sector had only been focused on parallel trade and exhaustion of rights issues.

43 See also furthermore Josef Drexl, Deceptive Conduct in the Patent World – A Case for US Antitrust and EU Competition Law?, in Patents and Technological Progress in a Globalized World – Liber Amicorum Joseph Straus 137, 147 (Wolrad Prinz zu Waldeck und Pyrmont et. al. eds., 2009).

44 See also Case T-62/98, Volkswagen AG v. Comm'n, 2000 E.C.R. II-2707 (discussing the importance of the definition of the relevant market).

45 See e.g. Suzanne Rab and Daphne Monnoyeur, European Commission Inspections in the Pharmaceutical Sector – Antitrust Scrutiny Continues, 14 Hogan & Hartson Life Sciences Competition & Antitrust Update 10, 12 (2009) (referring to the merger cases Teva/Barr and Sanofi-Aventis/Zentiva).

46 See supra note 7.

47 This is in contrast to merger cases, where a narrow market definition may help the merging parties as it makes horizontal overlaps of businesses less likely. See supra note 45 at p. 12.

48 See Case 85/76, Hoffmann-La Roche & Co. AG v. Comm'n, 1979 E.C.R. 00461; See also Hanns Ullrich and Andreas Heinemann, in Wettbewerbsrecht Vol. 1 Part 2, 162 (Ulrich Immenga and Ernst-Joachim Mestmäcker eds. 2007) (providing an overview of relevant ECJ jurisprudence on that definition).

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havior is assessed based on whether its actual or potential effects on the marketplace substantially harm (part of) intra-community trade. The assessment of both of these factors in a specific case involves thorough economic analysis, legal reasoning, substantial time and effort while still allowing a lot of leeway for a final judgment.[49] This in turn obviously is the source of high legal uncertainty – especially in the pharmaceutical industry due to its complex competitive forces (see chapter 3.2).

A controversially discussed issue in assessing Art. 102 TFEU abusiveness lies in the relevance of the underlying intent of a company's action. This is highly relevant for determining the legitimacy of generic defense strategies, as their objective – per definition – is to maintain or extend a company's competitive position in the marketplace: According to the *1998 World Cup*[50] and *Hoffmann-La Roche*[51] decisions, competition law evaluations of abusive conducts generally are supposed to be objective and neutral without considering the purpose or business rationale of a certain practice. Relevant is only the (potentially) resulting pro- and anticompetitive effects in the relevant marketplace. In contradiction to this, intent nevertheless can indirectly become relevant: According to the *Michelin II*[52] decision, intent easily proves or even presumes the existence of anticompetitive market effect in situations where the assessed conduct was designed for the sole purpose of excluding rivals. In those cases, no further evidence of an actual anticompetitive effect needs to be provided. This is also reflected in the EU Commission's guidance on Art. 102 TFEU enforcement priorities, according to which *"direct evidence of any exclusionary strategy [such as company-internal documents, will be considered insofar as this*] *may be helpful in interpreting the […] conduct"*.[53]

In any case, dominant firms do have special obligations when it comes to behavior in the marketplace.[54]

49 See supra note 9 at p. 585 referring to supra note 3.
50 See Commission Decision, Case IV/36.888, 1998 World Cup, 2000 O.J. (L 5) 55.
51 See supra note 48.
52 See Case T–203/01, Manufacture française des pneumatiques Michelin v Commission, 2003 E.C.R. II–4071.
53 European Commission, Competition DG, Guidance on the Commission's Enforcement Priorities in Applying Article 82 of the EC Treaty to Abusive Exclusionary Conduct by Dominant Undertakings, 2009 O.J. (C45) 7,10.
54 See Dieter Stauder and Pascal Böhner, Bericht über die Diskussion, in Sektoruntersuchung Pharma der Europäischen Kommission – Kartellrechtliche Disziplinierung des Patentsystems? 73, 78-80 (Bardehle Pagenberg Dost Altenburg Geissler eds., 2010).

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2.2.2. The Intersection of IP and Competition Law

Assessing a pharmaceutical company's behavior under competition law requires an extraordinarily careful approach by the respective authorities due to the tradeoff between static and dynamic economic efficiency, which will be discussed at length in chapter 3.2.[55] Perfect static competition, where the equilibrium price would equal only the marginal costs of drug, would not allow innovative pharmaceutical companies to appropriate superior returns required to recoup their R&D investments.[56] Dynamic competition would consequently be eliminated. *Jones* and *Sufrin* therefore argue that a functioning free market competition may require a certain degree of temporary dominance by a firm as long as the market is not (fully) foreclosed from the entry of new incumbents, which would then compete via substitutes.[57]

The promotion of dynamic competition is *inter alia* ensured by the legal regime of IP rights (see chapter 2.1.2.). Although the sector inquiry stresses conflicts between IP and competition law, it is decisive to understand that the primary intention of IP rights is to complement rather than to exclude EU competition law.[58] This however is not achieved– as the sector inquiry may imply – through IP and competition law being *in pari materiae* in the sense that they would share the common goal of facilitating innovation. More so, IP rights in general and the patent system more precisely, should be regarded as a sub-system serving the overall market economy by achieving progress through innovation.[59]

55 Whereas static efficiency considers resource allocation and welfare effects from the equilibrium price and quantity at a certain point in time, dynamic efficiency considers economic progress and welfare effects of market participants' behavior over a certain period of time. The resulting policy conflict is predominantly strong in pharmaceuticals due to the 'innovation dilemma' as discussed in chapter 2.1.1.

56 See e.g. Alison Jones and Brenda Sufrin, EC Competition Law Text, Cases, and Materials 3-10 (3rd edition Oxford University Press 2008) (providing a general overview of fundamental economic theories and competition law).

57 See Id. at p.586.

58 See Frank L. Fine, The EC Competition Law on Technology Licensing 14 (Sweet&Maxwell 2006).

59 See Hanns Ullrich, Wahrung von Wettbewerbsfreiräumen innerhalb der Schutzrechtsverwertung – Die Regelung des Innovationswettbewerbs im und durch das Patentrecht, in Sektoruntersuchung Pharma der Europäischen Kommission – Kartellrechtliche Disziplinierung des Patentsystems? 29, 42 (Bardehle, Pagenberg, Dost Altenburg, Geissele eds., Carl Heymanns Verlag 2010).

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In contrast to US antitrust law, the European understanding consequently does not see IP rights as an exclusionary zone not subject to competition law, but clearly as being fully in the scope of its regulation.[60] Nevertheless, the *Microsoft* decision[61] confirmed that the mere existence of IP rights does not automatically lead to a dominant market position. As *Ullrich* and *Heinemann* emphasize, the decisive criteria rather are under what circumstances the IP right holder becomes market dominant and what role the IP ownership plays in that respect.[62]

This perspective complemented the precedent cases of *Magill*[63] as well as *Bronner*,[64] where the ECJ concluded that the exercise of an IP right might indeed constitute an Art. 102 TFEU abuse, but only under 'exceptional circumstances'.[65] In these special situations, IP rights may be considered a 'bottleneck monopoly', or what the EU Commission calls an 'essential facility'. Thereby, access to a competitor's IP would be indispensable for the rival, as *'there is no actual or potential substitute'* for it.[66]

It therefore seems clear that there is nothing like an IP-induced general privilege in the application of Arts. 101 and 102 TFEU.[67] Nevertheless, *Drexl* observes that competition authorities are generally used to rather safeguard static competition and fight price cartels, whereas exactly this complex relationship between static and dynamic efficiency is what makes

60 Compare Commission Communication, Executive Summary of the Pharmaceutical Sector Inquiry Report 18-19 (Jul. 8, 2009) with Rainer Bechtold et al., EG Kartellrecht Kommentar Art. 81-86 EG, EG-Kartell-VO 1/2003 § 2009 (2nd edition, C.H. Beck 2009) (emphasizing that also restrictive business practices in the sense of Art. 101 TFEU do not constitute an exception to competition law).

61 See Case T-201/04, Microsoft Corp. v. Comm'n, 2007 E.C.R. II-03601, § 691.

62 See Ullrich & Heinemann, supra note 48 at p. 162.

63 See Case C-241/91 and C-242/91, Radio Telefis Eireann (RTE) and Independent Relevision Publications (ITP) v Comm'n, 1995 E.C.R. I-743, § 50.

64 See Case C-7/97, Oscar Bronner, 1998 E.C.R. I-7791.

65 See Joseph Straus, Patentanmeldung als Missbrauch der marktbeherrschenden Stellung nach Art. 82 EGV?, 2 GRUR-Int 93 (2009) (referring to the Magill decision).

66 See Irina Haracoglou, Competition Law and Patents – A Follow-on Innovation Perspective in the Biopharmaceutical Industry 133 (Steven D. Anderman et al. eds., Edward Elgar Publishing 2008) (referring to supra note 64 at § 38, 41 and 44).

67 See Press Release IP/04/382, European Commission, Commission concludes on Microsoft investigation, imposes
conduct remedies and a fine (Mar 24, 2004).

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it so hard for them to apply competition law to cases in the IP-heavy pharmaceutical sector.[68]

2.2.3. The 'More Economic Approach' to EU Competition Law

The EU Commission has advocated for applying a 'more economic approach' to competition law. This is characterized by differentiated case-by-case decisions rather than strengthening per-se rules. Moreover, the approach calls for balancing pro- and anticompetitive effects of the conduct under investigation not on overall social welfare, but rather on consumer welfare.[69]

Central aspects of the 'more economic approach' stand in conflict with ECJ jurisprudence and previously articulated opinions by the EU Commission, which has substantially contributed to even further legal uncertainty for the pharmaceutical industry: A focus on consumer instead of overall social welfare implications is not supported by the ECJ, which has made clear that competition law is supposed to protect competitive market structures rather than competitors or consumers.[70] *Straus* interprets the EU Commission's discussion paper on the application of Art. 82 of the EC Treaty (now Art. 102 TFEU) as also supporting this more traditional perspective: In the paper, the EU Commission would articulate the objective of protecting competition, not competitors.[71] The more traditional perspective is also supported by *Gassner*, who concludes with reference to the *GlaxoSmithKline* decision[72] that negative effect on consumer welfare should be consid-

68 See Josef Drexl, Pay-for-Delay – Zur kartellrechtlichen Beurteilung streitbeilegender Vereibarungen bei Pharma-Patenten, in Sektoruntersuchung Pharma der Europäischen Kommission – Kartellrechtliche Disziplinierung des Patentsystems? 13, 22 (Bardehle, Pagenberg, Dost Altenburg, Geissele eds., Carl Heymanns Verlag 2010).

69 See Dieter Schmidtchen, Der „more economic approach" in der europäischen Wettbewerbspolitik – Ein Konzept mit Zukunft, in Internationalisierung des Rechts und seine ökonomische Analyse 473, 473 (Thomas Eger et al. eds., 2008).

70 See e.g. Joint Cases C-501/06 P, C-513/06 P, C-515/06 P and C-519/06 P, GlaxoSmithKline Services Unlimited v. Comm'n (under appeal – not published yet, see Case T-168/01, GlaxoSmithKlineServices Unlimited v. Comm'n, 2006 E.C.R. II-2969.

71 See supra note 65 at p. 100.

72 See supra note 70.

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ered but should not be decisive in determining overall anticompetitive behavior.[73]

Nevertheless, even the application of this more traditional view may in practice be biased in favor of (short-term) consumer benefits: As *Etro* argues, quantifying effects e.g. from excessive pricing, which can be observed and measured, is much easier than determining implications on incentives to innovate, which would require a deeper evaluation.[74] The pharmaceutical industry thus may find it harder in the future to argue the legitimacy of behaviors which show substantial anticompetitive effects today but at the same time significant procompetitive effects on innovation in the future.

This bias is also mirrored in the public healthcare debate, where many economic studies – more or less successfully – have tried to quantify drug pricing effects from generic competition,[75] whereas few works have successfully empirically argued the effects on incentives to create pharmaceutical innovation.

2.2.4. The Sector Inquiry as an EU Competition Law Instrument

The EU Commission's pharmaceutical sector inquiry has further increased legal uncertainty for the pharmaceutical industry. The legal basis for this instrument can be found in Art. 17 of Council Regulation EC 1/2003, which generally allows the EU Commission to investigate for a specific sector on its own motion or acting on a complaint.[76]

In case of the pharmaceutical sector inquiry, the EU Commission *"suspected a potential systemic problem [with respect to] potential delays of market entry of generic companies"*.[77] Not surprisingly, the initiative was, *inter alia*, admittedly initiated by the European Generic Medicines Asso-

73 See Ulrich Gassner, Markteintrittsrelevante Vereinbarungen zwischen Original- und Generikaherstellern im Kreuzfeuer, 1 A&R 3, 9 (2010).
74 See Federico Etro, Competition, Innovation, and Antitrust, A Theory of Market Leaders and Its Policy Implications 186 (Pringer Verlag 2007).
75 See e.g. Michael C. Müller et al., Die Bedeutung der Generikaindustrie für die Gesundheitsversorgung in Deutschland (Accenture Management Consulting 2005), available at http://www.accenture.com/Countries/Germany/ Research_and_Insights/Generikaindustrie.htm.
76 See supra note 74 at p. 172 and supra note 10 at pp. 508-510.
77 Supra note 28.

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ciation (EGA).[78] The authors of the final report clarified that the sector inquiry's purpose was to assess pharmaceutical company's use of IP rights, mainly patenting behavior, which can in principle delay the market entry of others.[79] By that, authorities were supposed to gain a general understanding about potential anticompetitive behavior – quasi a fact-finding exercise as a basis for focusing further investigative priorities.[80] The final report is characterized by numerous disclaimers stressing that it does neither predetermine investigations of individual competition law cases, nor does it serve as competition law guidance.[81]

It surely is dissatisfying to the pharmaceutical industry that the report remains vague when it comes to practical implications – especially a frustrating experience considering the time, effort and uncertainty which was associated with it.[82] This frustration may have even been increased by the EU Commission's preliminary view on French sector inquiry participant *Les Laboratoires Servier*, which was alleged to have provided *"misleading and incorrect"* information during the inquiry, which triggered a severe fine of over 35 million €.[83] Some scholars, such as *Drexl*, criticize that the EU Commission has expressed concerns about certain company behavior without providing (sufficient) legal reasoning to justify these concerns.[84]

But what relevance would legal reasoning have in the context of the EU Commission's sector inquiry? The sector inquiry's insights may suggest and drive legislative action.[85] Although the EU Commission does not have

78 See Thomas Porstner, Patienten müssen am ersten Tag nach Ablauf des Patents sofortigen Zugang zu bezahlbarer generischer Medizin erhalten, in Sektoruntersuchung Pharma der Europäischen Kommission – Kartellrechtliche Disziplinierung des Patentsystems? 3, 3 (Bardehle, Pagenberg, Dost Altenburg, Geissele eds., Carl Heymanns Verlag 2010).

79 Compare supra note 10 at p. 239 with supra note 11 at p. 61 (criticizing this focus on market participant behavior and arguing, that solving any generic delay issue would need to determine the relevance of company behavior vis-à-vis other potential sources for delays, such as in the regulatory system).

80 See supra note 7.

81 See e.g. supra note 10 at p. 245 and p. 278 and p. 508. The EU Commission for example has already issued guidelines on use of practices on IP rights in the regulation on the application of Art. 101.3 TFEU to categories of technology transfer agreements.

82 See supra note 78 at p. 8.

83 See Kevin Grogan, Servier could be hit with hefty fine for 'misleading' EU (PharmaTimes Online Jul. 28, 2010), available at, http://www.pharmatimes.com/Article/10-07-28/Servier_could_be_hit_with_hefty_fine_for _misleading_EU.aspx.

84 See supra note 68 at p. 25.

85 See supra note 28.

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authority based on Art. 17 of Council Regulation EC 1/2003 to investigate for regulatory change, it is obliged to include any general insights gained into the political decision-making process.[86] When assessing implications for company behavior, it is therefore critical to understand that the EU Commission may believe it does not really need legal reasoning for justifying its concerns raised: Economic reasoning may be sufficient to trigger legislative change. The EU Commission acts, as *Etro* puts it, as a lawmaker, policy officer, investigator, prosecutor, judge and jury.[87]

Besides policy setting, the EU Commission's power was already demonstrated by individual post-inquiry investigations against pharmaceutical companies *Les Laboratoires Servier* and *Lundbeck* based on Art. 11 of Council Regulation 1/2003 as well as Art. 2 of Commission Regulation 773/2004.[88] Moreover, any future investigation may rely on the sector inquiry's insights, empirical evidence and argumentation to render appropriate jurisprudence.

86 See supra note 59 at p. 31.

87 The Court of First Instance (CFI) has jurisdiction in all actions against the decision of the Commission, while ECJ decides on CFI appeal actions. See supra note 74 at p.172.

88 See Press Release IP/10/08, European Commission, Antitrust: Commission opens formal proceedings against pharmaceutical company Lundbeck (Jan. 7, 2010) and Press Release MEMO/09/322, European Commission, Antitrust: Commission opens formal proceedings against Les Laboratoires Servier and a number of generic pharmaceutical companies (Jul. 8, 2009) as well as Suzanne Rab and Bróna Heenan, European Commission Launches Monitoring of Patent Settlement Agreements, 15 Hogan & Hartson Life Sciences Competition & Antitrust Update 12, 12 (2010).

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3. Competitive Dynamics in Europe's Pharmaceutical Market

After having analyzed policy and competition law approaches to Europe's pharmaceutical industry, this chapter now turns towards the subject matter itself: Market structure, business models and dimensions of competition in Europe's pharmaceutical sector are discussed to provide the economic and business reality under which generic defense strategies are developed and executed today.

3.1. Market Structure and Business Models

3.1.1. Market Relevance

Europe's market for human pharmaceutical products has developed into one of the most attractive sectors in the world: With almost 215 billion € worth of human pharmaceutical products in 2007, Europe spent on average 2% of its Gross Domestic Product (GDP) or approximately 430 € per citizen on pharmaceuticals.[89] By that, the EU represents approximately 30% all pharmaceuticals sold globally being the second largest geographic market (after North America) worth approximately 730 billion € in 2007. Although emerging regions as Asia or Latin America have sustainably outperformed Europe's growth rates of less than 6% from 2007 to 2008, the EU will remain a key priority for global pharmaceutical companies. This is mainly due to its mere size as well as its demand structure for expensive drugs with high therapeutic value represented by high drug expenditure per capita.[90]

Europe contributes 14 firms to the world's 50 largest pharma companies measured by sales in 2008. Headquartered in EU member states, they all run global business operations beyond the European market, which have generated over 180 billion US$ in global sales in 2008. Thereby, a relatively high market concentration can be observed: The three largest companies,

89 See supra note 10 at p.10 and p. 20; Figures include prescription as well as non-prescription drugs in retail prices.

90 See Anthony Raeside et al., World Preview 2016, EvaluatePharma Report 3 (May 2010).

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i.e. *GlaxoSmithKline*, *Sanofi-Aventis* and *AstraZeneca*, already contributed 110 billion US$ of sales in 2008 (see figure 2) despite the fact that none of them had participated in the latest wave of mega mergers and acquisitions.[91]

Top-50 Ranking	Group Name	Global Pharma Sales 2008 (US$ bn)	Global R&D Spend 2008 (US$ bn / % of sales)		Tier
2	GlaxoSmithKline	43,0	5,2	12,1%	
3	Sanofi-Aventis	38,7	6,5	16,8%	1
5	AstraZeneca	31,6	5,1	16,1%	
13	Bayer	15,1	2,5	16,6%	2
16	Boehringer Ingelheim	13,6	2,9	21,3%	
22	Novo Nordisk	8,6	1,5	17,4%	3
23	Merck KGaA	7,6	1,5	19,7%	
27	Servier	5,2	n/a	n/a	
30	UCB	4,3	1,1	25,6%	
32	Solvay	3,8	0,6	15,8%	
33	Ratiopharm	3,7	n/a	n/a	4
41	Menarini	3,1	0,3	9,7%	
43	Shire	2,8	0,5	17,9%	
45	Lundbeck	2,1	0,6	28,6%	
TOTAL		**183,2**	**28,3**	15,4%	

Figure 2:
European Pharmaceutical Companies amongst the Global Top-50 Ranking 2008[92]

3.1.2. Originator Pharmaceutical Companies

Except for Germany's *Ratiopharm*, which was acquired by *Teva Pharmaceuticals* in 2010, all European pharmaceutical companies amongst the largest global 50 can be considered 'originators': They invest a substantial part of their revenues, on average over 15% (see figure 2), into R&D with the objective to discover, develop and commercialize innovative pharmaceutical products. In this effort, originators historically have focused on 'blockbuster' products in high prevalence disease areas with potential annual sales beyond 1 billion € in order to recoup their high investments and generate the expected profit level.[93]

For originators, profitability needs to be sufficiently high to fund R&D investments for both, drug candidates reaching the market as well as the much

91 In this recent wave, Pfizer acquired Wyeth, Novartis acquired Alcon, Merck & Co. acquired Schering-Plough and Roche gained majority control over Genentech. See PharmExec Staff, The PharmExec 50, 5 Pharmaceutical Executive 68, 70-78 (2009).
92 Own illustration; data sourced from Id. at pp. 70-78.
93 See supra note 10 at pp. 27-28.

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higher number of unsuccessful R&D projects, which have to be terminated before or during clinical trials due to safety and/or efficacy issues.[94] The fact that significantly more drug development candidates are abandoned than successful in turn requires higher profit contributions from those remaining successful drugs which meet the regulatory hurdles established to ensure patient safety. In case regulatory authorities also limit prices and thus the basis for those higher profits,[95] originator companies run the risk of getting 'squeezed'. Consequently, generic defense strategies are an important component of an originator's business model, as it allows to appropriate incremental returns from products launched on the market.

Pressure on profitability is even greater as originators also need to compensate demanding shareholders: Capital markets theory regards shareholders as residual claimants, who are only compensated after all other claims (e.g. wages of employees or interest payments for debt holders) have been satisfied by the company. Shareholders therefore demand returns for their provided capital adequately considering the inherent high risk and volatility of an originator's business model (figure 3 demonstrates the volatility of returns of individual originators).[96] In other words: Even after the consideration of R&D expenses, originator business models per definition need to generate profit levels significantly above those of other industry sectors in order to attract and retain capital. Otherwise, investors would pursue alternative opportunities with a lower risk profile and similar returns. As figure 3 shows, some European originators achieved returns on invested capital (ROIC) between 30-40% in 2005-2007, while average performers lie between 15-25%.

94 See supra note 4 at p. 432.

95 Such measures have been frequently adopted across many EU member states, e.g. by introducing price caps on pharmaceutical products (also see chapter 2.1.1.).

96 See Stephen A. Ross et al., Corporate Finance 391 (6th int. ed., McGraw-Hill Higher Education 2002) (1988).

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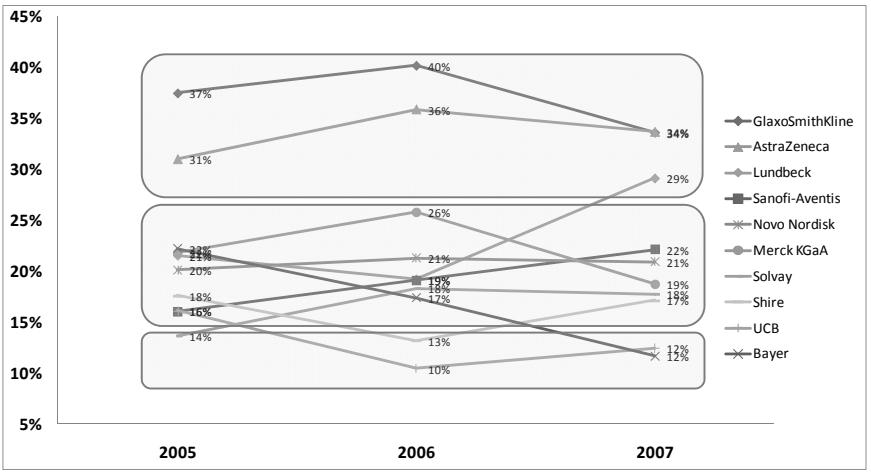

Figure 3:
ROIC 2005-2007 of publicly listed European originator companies amongst the Global Top-50[97]

3.1.3. Generic Pharmaceutical Companies

Besides the traditional originators, generic companies have emerged, which pursue a substantially different business model: Their objective is to 'imitate' established or mature products, i.e. drugs which have already been marketed by originator companies over a long period of time and have or will be soon subject to LOE.[98] Thereby, generic companies 'take over' the (manufacturing and) commercialization of such products in the most cost efficient way and thus ensure certain stability in supplying these products to patients.[99]

In contrast to counterfeits, which are illegal copies not subject to any quality control,[100] generic pharmaceuticals are legitimate copies subject to rigid regulatory approval processes. By proving bioequivalence vis-à-vis the originator's reference drug, generics are allowed to rely on the clinical

97 Data provided by Accenture Management Consulting research; invested capital used to compute ROIC does not consider capitalized goodwill; company selection based on supra note 91 at pp. 70-78 (only publicly listed companies considered).
98 See supra note 1.
99 See supra note 78 at p. 4.
100 On this confusion, see Kevin Outterson, Counterfeit drugs: the good, the bad and the ugly, 16 Alb. L.J. Sci. & Tech. 526 (2006).

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safety and efficacy data produced in course of the marketing authorization process.[101] R&D efforts therefore are substantially lower compared to originators, which consequently also leads to a more favorable risk profile and substantially leaner cost structure.[102] As a result, generics need to generate profit levels just over marginal costs of bringing the generic drug on the market. These need to be sufficient to finance investments into e.g. manufacturing and supply chain capabilities, as the ultimate objective is to optimize operations and use scale efficiencies to minimize the costs of goods sold (COGS). In line with the lower risk involved, expected shareholder returns are therefore also lower compared to investments in originator companies.

In comparing cost structures, the sector inquiry emphasizes the substantially higher costs for marketing and sales of originator companies. Without explicitly saying so, the final report appears to link these additional marketing costs to allegedly more aggressive commercial behavior of originator companies in the marketplace. The EU Commission seems to suspect that the performance of some originator companies would be based on marketing tactics rather than innovation, constructing a conflict between investments into R&D and marketing and sales.

A more differentiated view would however rather argue that generic companies do not have lower marketing and sales costs because they are less aggressive in the marketplace. As generics sell over price rather than innovation, they simply cannot afford higher marketing costs in order to be able to compete against each other. From the originator's perspective, R&D investments often trigger or correlate with marketing and sales investments: Innovative products are scientifically complex and novel and thus require substantial efforts to explain to physicians the area of application, therapeutic effects and potential issues e.g. related to multi-morbidity. One should thus keep in mind, that generic products therefore partially not only 'free ride' on originator's R&D investments by imitating established science, but also on originator's commercial efforts, as established products sell much easier than newly launched innovative products.

In 2007, the generic segment represented approximately 18% of the value of EU's human prescription drug market worth approximately 22 billion

101 See supra note 10 at pp. 39-40.
102 See Id.

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EUR on an ex-factory basis.[103] Interestingly, only one European generic company, i.e. Germany's *Ratiopharm*, is represented within the Top-50 pharmaceutical companies. Beyond this, only four other non-EU generic companies appear on the list, i.e. *Teva*, *Mylan*, *Watson* and *Actavis*. Except for *Teva*, all of them generate global annual sales significantly below 5 billion US$. This confirms the sector inquiry's finding of generic companies being generally smaller and more localized compared to originators.[104] One should however not forget that approximately 40% of the total worldwide generic sales in 2007 was generated by two market leaders: Israel's *Teva* as well as *Sandoz,* originator *Novartis'* own generics division.[105]

3.2. Dimensions of Competition

Originator and generic companies compete within Europe's common market. However, available legal protection instruments for innovative drugs as outlined in chapter 2.1.2 require a more differentiated consideration of existing competitive forces in order to effectively analyze the sector inquiry's findings.[106] Before the discussion turns towards potential limitations of generic defense strategies, this chapter therefore discusses the difficulties involved with dynamic competition on the one and static competition on the other hand.

3.2.1. Dynamic Competition for Substitution by Innovation

Dynamic competition is what the traditional originator business model is all about: Different market participants compete for product substitution by inventions, not by imitation of the same invention. Originator business strategies therefore 'race for innovation' to launch a first-in-class patent protected product with effectively no substitutability ('first to discover, first to patent').[107] *Etro* calls this a 'winner-takes-all' race. In contrast, patent

103 See supra note 11 at p. 59.
104 See supra note 91 at pp. 70-78 as well as supra note 10 at p. 37.
105 See Eyal Desheh, Chief Financial Officer, Teva Pharmaceuticals and Bill Marth, President and Chief Executive Officer, Teva North America, Presentation at the 27th annual JP Morgan Healthcare Conference: Introducing the World Leader in Generic Pharmaceuticals (Jan. 12, 2009).
106 See supra note 10 at p. 25.
107 See Id. at p.25 and 379.

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protected drugs in areas where treatment already exists need at least to be 'best-in-class' by providing superior treatment profiles in order to be commercially successful.[108] Demand for such products can however be attracted away by alternative patent protected products as well as by already existing generic versions of such alternative therapies. This illustrates why *"[p]atents grant a legal monopoly that cannot necessarily be equated with an economic monopoly."*[109] In the vast majority of cases, innovative drugs are in direct competition with different patented and generic products for the same treatment even prior to LOE.[110] The maximum time for a new drug's successful commercial exploitation thus is less determined by the term of protection prior to LEO, but rather by the degree of dynamic competition.

Originator products (i.e. innovative pharmaceuticals) are nevertheless predominantly defined by their ability to meet patentability requirements in major jurisdictions: A new patentable active ingredient protecting a drug not marketed before clearly is the result of dynamic competition. A rather grey and undefined area relates to products which are (only) able to provide additional (medical) use or a more beneficial application over existing reference products, but are not able to enjoy patent protection.[111] A broader definition of innovation and dynamic competition would also include products complementary to already existing reference products, which competing firms develop or would want to develop.[112] In contrast to this, a product which only achieves a lower price level on the market without any other additional therapeutic value over an existing reference product can be clearly regarded as static competition for imitation.

This distinction is critical when it comes to alleged anticompetitive effects associated with generic defense strategies: The foreclosure of static competition via IP rights (during the term of protection) has to be considered legitimate.[113] Competition law governing the patent system normally also accepts loss of competition in case of true dependencies between main in-

108 See supra note 74 at p. 26.
109 Supra note 66 at p. 120.
110 See supra note 10 at p.25.
111 This may be the case for example due to lack of inventive step, which would make the invention obvious.
112 See supra note 41 at p. 169.
113 See supra note 13 at p. 416.

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vention and incremental inventions.[114] As *Schnelle* argues, EU competition law may however consider practices of dominant IP right holders abusive where they have a substantial limiting effect on dynamic competition for innovation. Such competition, which is based on specific techniques, technologies or standards, thus is also safeguarded by competition law even against exclusive IP rights.[115] As *Drexl* puts it: *"'Successful' innovation is allowed, and is even expected, to override inferior technology and to win market dominance. However, such dominant positions in a competition-oriented IP system should remain contestable."*[116]

The boundaries of such cases obviously depend on the underlying definition of pharmaceutical product innovation. This general issue is indeed substantially more complex for drugs than for other goods, as some drugs may not be able to achieve patent protection, but still provide incremental therapeutic improvements, which is a classical line of argumentation by generic companies.

3.2.2. Static Competition for Imitation of In-Market Products

In contrast to dynamic competition, static competition optimizes the allocative efficiency of resources at a certain point in time by driving down prices to marginal costs. Although this is what theoretically happens at a drug's LOE, in reality, a certain minimum level of static inefficiency is system-immanent. The reason lies in the European public healthcare system being built around the principle of solidarity. This system is faced by a typical principal-agent dilemma: While physicians and patients decide about a specific therapy, associated costs are borne by others, i.e. the health insurance.[117] The health insurance as the principal thus is unable to control the necessity of drug prescription and consumption by the agents, i.e. physi-

114 This is because a refusal to license an invention to a dependent patent holder generally is legitimate (however with exceptions as outlined in chapter 4.2.1.); see supra note 59 at pp. 43-44.

115 See supra note 41 at p. 169.

116 Josef Drexl, Responding to the Challenges for Development with a Competition-Oriented Approach, in 1 International Centre for Trade and Sustainable Development, Views on the Future of the Intellectual Property System 17, 19 (John H. Barton et al. eds., 2007).

117 See supra note 68 at p. 17 and supra note 10 at p. 28 and p. 46.

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cian and patient.[118] What follows is a problem of moral hazard, whereby drug prescription is suboptimally high as the responsible parties have no clear interest to behave more efficiently.[119]

The effects of static competition at LOE need to be considered in light of the characteristics of the information and knowledge necessary to develop an innovative drug: The science associated with the development as well as any clinical trial results can be regarded as public goods: Existing products are normally relatively easy to imitate through reverse engineering – the first mover advantage for a new product would therefore be too short to recoup investments without any IP protection.[120] Consequently, at LOE, generic market entry initiates so called 'hyper-competition' on the price dimension, which is why legislators regard generic companies as the key factor in realizing associated cost reductions for public healthcare systems in EU member states. According to the sector inquiry results, initial price levels for generic products are on average 25% below the originator's reference product (if compared prior to LOE). This level drops even further to an average of 40% two years after the first entry.[121] On the one hand, this is what originator companies frequently call the 'patent cliff' which they need to find ways to sail around in order not to lose substantial revenues and profits. On the other hand, static drug competition has contributed around 3 billion EUR in healthcare cost savings between 2000 and 2007, which underlines the EU Commission's motivation to fight any delayed generic market entry, which would strain healthcare budgets and – ultimately – all tax payers funding this system.[122]

As originators are not interested in competing with generics and therefore sometimes take established products off the market post LOE,[123] one may stress the 'downstream' character of generic companies: Are originators

118 A similar principal-agent problem also exists between physician and patient, see e.g. Richard G. Frank, Behavioral Economics and Health Economics 7 (Yrjo Jahnsson Foundation, 50th Anniversary Conference on Economic Institutions and Behavioral Economics, May 20, 2004).

119 See Udo Schneider, Kostenfalle Gesundheiswesen? Ökonomische Herausforderung und Perspektiven der Gesundheitssicherung 14 (University of Bayreuth, Discussion Paper No. 08-03, 2003).

120 See supra note 13 at p. 42.

121 See supra note 10 at p. 78, § 212.

122 See supra note 14 at p. 432, supra note 28 as well as supra note 10 at p. 373.

123 Those are cases where the remaining profits reduced by price competition are too small to justify the remaining commercialization efforts.

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and generics in a vertical rather than a horizontal competitive relationship? While originators invent and develop new drugs, generics improve manufacturing and optimize distribution efficiency, which may be regarded as a different, subsequent type of business. Such an argumentation would allow originators more room to maneuver in applying generic defense strategies before being in conflict with competition law. This is because the prerequisite of market dominance would be harder to satisfy due to a necessarily broader definition of the relevant market. Nevertheless, as already outlined in chapter 2.2.1., the sector inquiry has made clear that the EU Commission wants to build on the *AstraZeneca* case, which had adopted the more traditional horizontal relationship.

In response to the EU sector inquiry, it cannot be overemphasized that an originator's attempt to attenuate static competition should in general be regarded as a legitimate interest:[124] Like in any other industry, the fundamental purpose of modern business strategy is to build, maintain and expand competitive advantages in the marketplace. It is therefore worrying that the sector inquiry, as well as scholars like *Schnelle*, carticulate the concern, that the patent system may be used as a 'strategic instrument'.[125] In a work done for the EU Commission, *Harhoff et al.* define the strategic use of the patent system as "*whenever firms leverage complementarities between patents in order to attain a strategic advantage over technological rivals."*[126] As *Harhoff et al.* correctly emphasize, this generally should not provide any guidance for *per se* anticompetitive behavior:[127] Why should a strategic approach to IP generally be more illegitimate than the use of other property rights? Ultimately, the purpose of defending against generics is to damp threats of static competition and generate profits from existing products with the goal to fully focus on the core of an originator's business model: Develop innovative pharmaceuticals in dynamic competition for scientific progress with other originator companies. As this legitimate objective should be generally acknowledged, it feels extraordinarily hard to define the boundary of anticompetitive behavior.

124 See supra note 68 at p. 27.
125 See supra note 41at p. 169.
126 Dietmar Harhoff et al., The strategic use of patents and its implications for enterprise and competition policies 78-80 (final report, Tender for No. ENTR/05/82, Jul. 8 2007.
127 See Id. at p. 79.

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3.3. Entry of Generic Competition

LOE and static competition are triggered by generic entry. In order to understand the approach a generic defense strategy needs to take, it is necessary to highlight some aspects on drivers and timing of generic entry.

3.3.1. Key Drivers for Generic Entry

Generic companies predominantly enter market segments with large potential volume sales as profits per product are rather low. Thereby they capitalize on the reference product's market by focusing on the most commonly sold product formulations – on average 2 to 2.5 generic formulations compared to the originator's product variety of 3.5 to 4 formulations. Only subsequently, they enter into line extensions, e.g. develop additional formulations, dosage forms or delivery methods.[128]

From a geographic dimension, generics prioritize EU member states in which generic drug demand is high, e.g. due to a large relevant patient population, low affordability of originator drugs or favorable national healthcare legislation (e.g. through compulsory generic substitution in the pharmacy or non existing generic price caps).[129] The sector inquiry concludes that national healthcare legislation is the single most important driver of market attractiveness for generics.[130] This explains the unevenly distributed generic penetration rate within the EU: While 61% of all pharmaceutical sales in Poland 2007 were generics, penetration in Spain was only 7.2%.[131]

Consequently, overall generic threat and the need for an originator to defend its positions are targeted towards the 'backbone' of an innovator's business: Blockbuster products in the most attractive markets.[132] The sector inquiry has identified cases where such single products are responsible for almost 20% of an originator's global annual sales.[133]

128 See supra note 10 at p. 36 & 69 & 77.
129 See supra note 7 as well as supra note 10 at p. 44 and 61.
130 See supra note 10 at p. 36 and p. 61.
131 See European Federation of Pharmaceutical Industries and Associations (EFPIA), The Pharmaceutical Industry in Figures (2009).
132 See chapter 3.1.2. about the definition and relevance of blockbuster drugs for originator business models.
133 See supra note 10 at p.16, p.27, p.67 and p.69.

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3.3.2. Timing of Generic Entry

Stiff price competition within the generic segment itself, which *Porstner* argues has been largely ignored by the sector inquiry, is the main motivator to *inter alia* challenge originators' patents and enter a market as early as possible. Once the attractiveness of a potential generic version of an established product is assessed, generic companies strive for entering the segment as the first one in order to appropriate as much return as possible in an oligopolistic competition against the originator's established product until other generic entrants come in (i.e. 'first mover advantage').[134] In contrast to the US regulatory system, which allows the first generic under special circumstances to benefit from an additional 180-day exclusivity period vis-à-vis other generic market entrants, the 'first mover advantage' in Europe is small: Average generic penetration rates are already 25% in value just one year after first generic entry, which then increase to 38% one year later.[135]

The sector inquiry provides extensive empirical evidence that proves a first generic product – on a weighted average – being available 7.9 months after the LOE of the reference product.[136] The difference between first generic market entry and LOE is defined as 'time to entry'. The EU Commission therefore generally strives for a situation where generics would be available on the first day after LOE and consequently considers the full 7.9 months as 'delay'.[137] This very narrow understanding seems to reflect an ambitious goal, is however line with European patent law, where the Bolar exemption is also supposed to facilitate an early-as-possible transition from market exclusivity towards stiff static price competition after patent expiry (see chapter 2.1.2).[138]

One fact pattern however remains interesting: For the 20 most valuable drugs, generic market entry is 45% faster, i.e. only takes 4.2 months post LOE.[139] As generic companies prioritize their investments to enter a product

134 See supra note 78 at p. 5.
135 See supra note 10 at p. 87.
136 See supra note 14 at p. 432 as well as supra note 78 at p. 7.
137 To what extent a 'day-1' availability for generic drugs would be realistically achievable and how big the lever of improving regulatory procedures really is does not lie within the scope of this thesis.
138 See supra note 59 at pp. 43-44.
139 See supra note 7.

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market according to the relative importance of that product in terms of expected sales and profitability, it seems that part of the general observable delay can be attributed to differentiated efforts by generics in entering a specific market.[140]

140 See supra note 54 at pp. 73-74.

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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.

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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.

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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.

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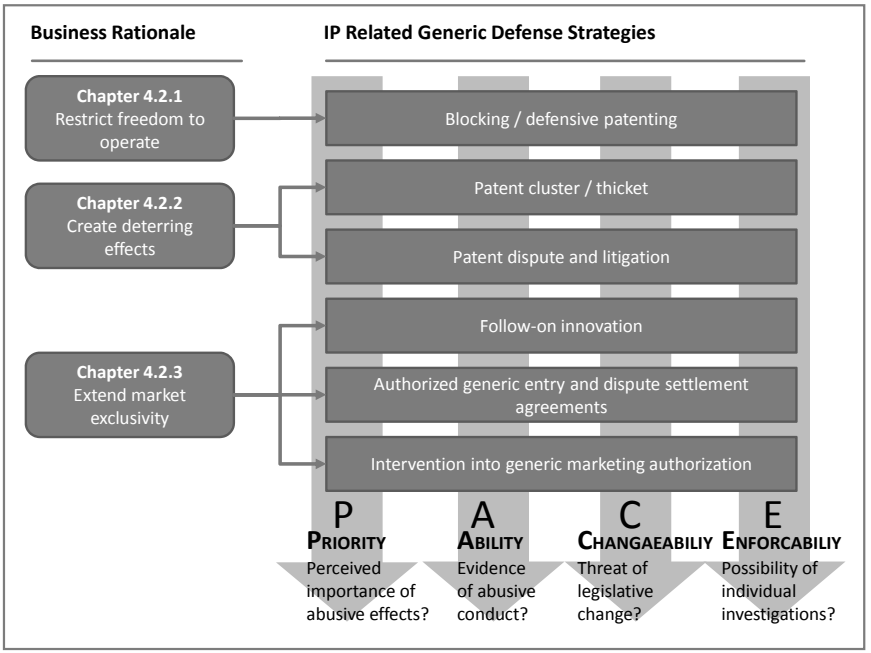

Figure 4:
Structure of analysis - IP related generic defense strategies as addressed by the sector inquiry according to their underlying business rationale and the PACE framework.

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.

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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.

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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.).

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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.

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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.

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be a misleading and artificially inflated number counting national patents instead of EU-wide patent families.[178]

From a defensively motivated perspective, patent thickets significantly reduce originator's dependency on the invention's basic patent, which may be invalidated or circumvented easily otherwise.[179] The sector inquiry regards this as a strategy to build several different layers of defense ('multi-layer defense'), which thereby also serve an aggressive-offensive purpose by building the foundation for using other IP related generic defense strategies, especially when it comes to litigation (see chapter 4.2.2.2.).[180] For generic competitors, broad patent thickets reduce the ability to imitate an originator's product easily by increasing complexity and transaction costs for market entry: Generics would have to invalidate or circumvent each patent in every single country they target. The EU Commission therefore calls this 'trapping generics' and expresses its concerns on the one hand about effects from granted patents, but also about effects from intentional delays of a patent application's final decision, e.g. via filing multiple divisional applications. Even if those rights would later not necessarily be granted, they still increase risk and uncertainty for any generic competitor observing such behavior.[181]

From an economic perspective, the key determinant would be whether the negative effects on dynamic competition associated with the higher transaction costs for generics' market entry exceed the positive effects on dynamic competition from improved diffusion of new knowledge via the patent system's disclosure function. If negative outweigh positive effects, it would be advisable to render such behavior anticompetitive. It is obvious that such a test could not be reliably conducted in a competition law case. It is difficult for competition authorities to intervene into such behavior as any potential anticompetitive effects are created by the mere existence of such rights, which – as discussed above – is normally not sufficient to be abusive: Deterring effects do not necessarily require a conduct of exercising

178 See supra note 41 at p.169 as well as supra note 7.

179 See Dietmar Harhoff, Head of Institut für Innovationsforschung, Technologiemanagement und Entrepreneurship, Ludwig-Maximilians-Universität Munich, speech at the anniversary event '30 Jahre Monopolkommission': Innovationen und Wettbewerbspolitik – Ansätze zur ökonomischen Analyse des Patentsystems (Nov. 5, 2004).

180 See supra note 10 at pp. 184-188 and p. 373 and supra note 126 at p. 7.

181 See supra note 10 at pp. 187-193 and pp. 453-455 as well as p. 512 and supra note 13 at p. 91.

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exclusionary power – the mere information asymmetries and potential effort involved in thinning out such thickets are sufficient.

An associated issue can be found in the Art. 102 TFEU prerequisite of a dominant position: At the point of applying for patents to build a thicket, originators most likely would not hold a dominant position yet. Consequently, the anticompetitive conduct would be maintaining a patent thicket rather than initially building it.[182]

So could competition authorities succeed by proving strong anticompetitive intent associated with maintaining the patent thicket, e.g. by accusing the originator to raise a generic rival's cost base? On a macro level, the sector inquiry suspects exactly such intentional behavior and provides evidence for a diverging trend between increasing pharmaceutical patent applications on the one side and a slowdown of granted marketing authorizations on the other side.[183] Besides substantial statistical difficulties with this evidence,[184] proof for such an allegation seems unrealistic on an individual company (micro) level: Pharmaceutical R&D does not search for individual patentable inventions, but for metabolic and clinical pathways, technologies and combinations of multiple pharmacological features which can be combined into a single new drug. Clustering different inventions, which are separately protected, into one single product thus lies in the nature of (bio)medical science, which may lead to something which might look like a 'thicket'.[185]

Also patent law itself does not change the picture, as patentability does and should not consider any criteria associated with anticompetitive effects of granting such rights.[186] In contrast to this, the inquiry's report is explicitly concerned about deterring effects from weak patent rights, where the patentee knows about the invalidation risk, but not the generic competitor. The EU Commission seems to imply anticompetitive conduct being associated with intentionally applying and exercising a knowingly weak patent.[187] Their understandable concern lies in deterrence purely associated with in-

182 See Hanns Ullrich, Professor emeritus, Max-Planck-Institute, speech at the MIPLC Trilateral Patent Law Conference (May 14, 2010).
183 See supra note 10 at pp.163-164.
184 The figures e.g. do not consider patent families but count them as separate ones and also considers those which are later invalidated.
185 See supra note 59 at p. 48.
186 See supra note 14 at p. 432.
187 See supra note 10 at §§ 503-505.

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formation asymmetries. Nevertheless, such a perspective seems irritating as it would effectively use competition law to review the quality of patents, for which patent law already has own control measures.[188]

The above mentioned arguments as well as existing case law by the *Tetra-Pak II*[189] decision seems to allow the conclusion that patent thickets alone should normally not be in conflict with current EU competition law. *Ullrich* correctly remarks that a useful assessment of anticompetitive effects in such cases should anyways be only done considering building and maintaining thickets together with other procedural and/or patenting behavior of that undertaking.[190] The uncertainty associated with cumulative use of generic defense practices – as outlined in chapter 4.1 – may thus play a predominant role in assessing limitations of patent tickets. Furthermore, systemic change in patent law may limit future behavior in this key aspect of generic defense strategies.

4.2.2.2 Patent-Related Disputes and Litigation

Building on patent thickets, the subsequent step for generic defense is to offensively use such patent portfolios for infringement litigation against generics. The sector inquiry suspects that potential interim injunctions and damage claims against a generic entry acts as a significant deterrent.[191] Thereby, signaling to generic competitors that any infringement will not be tolerated can be achieved even if the patent at dispute may subsequently be revoked or amended in opposition.[192]

One needs to keep in mind, that it is the exact purpose of any enforcement action related to a property right, including IP, to protect a (legal) monopoly created in the first place – in a pinch through litigation. Litigation in general is rather – guaranteed by the *European Convention of Human Rights* – a legitimate and fundamental right.[193] The sector inquiry nevertheless suspects that originators may not always bring a court case against a generic

188 See supra note 12 at p. 31.
189 See Case C-333/94 P, Tetra Pak International SA v. Comm'n, 1996 E.C.R. I-05951.
190 See supra note 59 at p. 34.
191 According to the final report, a main infringement process on average takes 2,8 years whereas a generic's counterclaim for invalidity may not be enough to prevent interim measures. See supra note 10 at pp.205-220.
192 See supra note 10 at pp. 107-108 and p. 199 as well as p. 369.
193 See supra note 7.

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competitor in pursuit of the merits of an individual patent claim, but rather (only) as a deterrent signal to potential entrants: By drawing generic competitors into 'unnecessary' legal disputes, originators would purposely raise – or at least threat to raise – their rival's cost base, even if the generic competitor ultimately succeeds in these disputes. According to the final report, this effect would be especially relevant where multiple parallel legal cases are brought against generics in different EU jurisdictions.[194] During the period under review by the sector inquiry, the number of patent disputes in the EU has quadrupled, which is however no indicator whatsoever without a substantial cross-industry comparison: Are 700 started litigations in relation to over 200 investigated drug compounds in eight years and 27 EU member states 'too much' or a signal for abnormal behavior? As demonstrated in previous chapters, the pharmaceutical sector is a highly competitive and aggressive industry, where legal disputes in a high frequency are likely to be expected.[195]

Originators to a certain extend are even required to bring similar cases in different jurisdictions when they effectively want to defend their IP rights. This is not necessarily due to abusive intent, but more due to the current imperfections of the judicial patent law system in Europe with respect to inabilities for consolidating cross-border litigation into a single case: Despite the theoretical possibility provided by Art. 6.1 of the 'Brussels Regulation' 2001/44/EC,[196] patent infringement since the *GAT v. LuK* decision requires individual court cases in different EU jurisdictions, even if they address the same patent family, parties and business conduct. As those cases normally do not qualify (anymore) as being 'closely related' due to the bundle of separate national patent rights, individual national courts have to decide based on *lex loci protectionis*. Multiple separate cases with conflicting decisions concerning the same facts are consequently no exception.

European competition law does however provide an established limitation to the pursuit of litigation for dominant originators qualifying as an Art. 102 TFEU abuse: The case of vexatious or frivolous litigation as established in the *ITT Promedia* decision, which allows interventions however only in 'wholly exceptional circumstances'.[197] According to *Lord Jus-*

194 See European Commission, supra note 60.
195 Compare supra note 68 at p.17 and supra note 59 at p.35. and supra note 11 at p. 54.
196 Also known as the 'spider in the web' doctrine.
197 See Case T-111/96, ITT Promedia NV v Commission, 1998 E.C.R. II-2937 as well as supra note 5 at p. 8.

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tice Jacob, "only if there is vexatious litigation should there ever be a competition law intervention".[198] Under this doctrine, clear cases to be avoided by originators are those where litigation's purpose would be solely to harass or hinder the generic competitor as part of a plan to block its market entry.[199] This situation normally is given where the litigation *"cannot reasonably be considered to be an attempt to assert what the plaintiff reasonably believes to be its right."*[200] The difficulty with this test in generic defense situations obviously lies in the complexity of pharmaceutical patents, where a genuine dispute about an infringement allegation will almost always exist.[201] The doctrine's application should thus – if it remains unchanged – likely play into the hands of originators, except for 'whistleblower' situations where authorities can present clear and convincing evidence (e.g. internal company documents) about the existence of anticompetitive plans and strategies.[202]

Although the issue in general is not flagged for follow-up by Competition DG, *Priddis* and *Constantine* nevertheless see a potential threat if the EU Commission would want to combine the vexatious litigation doctrine with its general problem associated to weak patents: Vexatious intent may be proven more easily where it can be shown that the underlying patent right was weak, so that the originator clearly only would have used litigation to raise rival's costs and deter market entry. It feels highly uncomfortable to imagine a situation where the alleged originator would not only need to show its genuine attempt to assess infringement, but that it also initiated litigation with good prospects of succeeding in court.[203]

4.2.2.3 Implications from Future Patent System Reforms

Besides the intent to enforce competition law against individual undertakings, the inquiry's final report articulates high hopes for a unitary pan-European patent law system as being the solution for many of the discussed issues – quasi a 'magic bullet' against abusive generic defense strate-

198 Quoted according to supra note 11 at p. 70.
199 See Case T-111/96, supra note 197 at § 55.
200 Supra note 12 at p. 31 referring to supra note 197.
201 See supra note 12 at p. 31.
202 See supra note 9 at p. 587.
203 See supra note 12 at p. 31.

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gies.[204] Indeed, a single patent court as proposed by the European Patent Litigation Agreement (EPLA) for example could substantially reduce forum shopping and other litigation tactics, while the introduction of a Community patent would drastically reduce patent thicket building options.[205]

Major patent reforms have however been discussed since decades and many constructive proposals have not found their way through the political decision making process. Although the final report claims the contrary, it is still not evident that a unitary patent system in Europe is welcomed by all stakeholders involved. For originators seeking patent protection, the Community Patent indeed would e.g. eliminate costly and burdensome national patent validation and renewal procedures.[206] However, originators would also face a much higher risk of consolidating patent validity decisions for the whole European marketplace into one single court decision.[207] Legislation has recognized this perspective and is utterly concerned about potential chilling effects on innovation not only across the pharmaceutical but also many other patent-heavy industry sectors.[208]

Besides above mentioned large reform plans, incremental change is driven forward by the EPO. During the sector inquiry, the EPO had already confirmed that certain practices outlined above, such as defensive patenting, may not be in line with the patent system's policy objectives.[209] As a practical reaction to the inquiry's findings already in March 2009, the EPO triggered an EPC amendment limiting possibilities and time periods during which voluntary divisional patent applications can be filed. This demonstrates the impact the sector inquiry already had and will continue to have in shaping the European patent system, whereby EPO's 'raising the bar' initiative will continue to play a major role in fine-tuning certain aspects.[210] The EU Commission has already articulated that it would also like to see stricter procedural rules and shorter time limits in the area of patent opposition and appeal procedures.[211]

204 See supra note 10 at § 1578 as well as supra note 14 at p.437.
205 See supra note 10 at p. 164 and p. 443 and p. 525.
206 See supra note 10 at p. 442.
207 See supra note 54 at p.76.
208 See supra note 12 at p. 30.
209 See supra note 10 at p. 512.
210 See supra note 10 at p. 512.
211 See supra note 10 at § 1340.

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4.2.3. Extension of Exclusivity Terms

Besides the creation of deterring effects, the maximization of the exclusivity term prior LOE, during which generic competitors cannot effectively compete, is at the heart of any IP related generic defense strategy. In this area, the sector inquiry identifies three practices, which the EU Commission finds concerning and allegedly anticompetitive. All of these strategies do include essential patent-related aspects; their potential future limitations are discussed below.

4.2.3.1 Revitalization through Follow-On Innovation

As outlined in chapter 3, originator business models require a constant introduction of new inventions to the market in order to commercialize products under exclusivity. Sometimes those inventions are radically innovative drugs with new treatment for a disease with high unmet medical needs. Inventions can however also constitute 'follow-on innovation', i.e. only incremental improvements of already existing drugs, e.g. by further improving the safety and efficacy profile. In most cases – as science often does develop incrementally by building on prior art and own previous inventive work – the therapeutic profile of such new products is very close to the existing 'first generation' product commercialized by the same originator.

The sector inquiry has articulated the well-known criticism that, should the follow-on innovation qualify for a patent, the originator would benefit from an 'unjustified' extension of its exclusivity term through 'evergreening'. Although no (legal) obstacles exist for a generic to imitate the first-generation product post LOE, incremental follow-on innovation would be used to switch patients to the new, arguably better product before LOE of the old one is reached. From the sector inquiry's perspective, this would often just be an 'overhaul' of the existing product.[212] The revitalization of exclusivity may be achieved by developing different formulations or physical forms of an existing product.[213] Patents, which protect this follow-on innovation, are referred to as 'secondary patents' in the final report, although it was acknowledged that this term is not technically established in patent law and

212 See supra note 10 at § 987ff. as well as supra note 9 at p. 589.
213 See supra note 10 at p. 165 and p. 357.

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does not imply lower quality, but are just filed after the basic patent.[214] The EU Commission feels confirmed when it quotes that almost 80% of all legal patent disputes involve secondary and not basic/primary patents.[215] *Ullrich* and others have joined into the EU Commission's perspective in alleging there would be something like 'patenting as necessary', which would allow a patent being granted not at the time of invention, but whenever required, i.e. ideally shortly before the first generation product's LOE.[216] This hypothesis was however falsified by evidence provided in the final report itself, which shows that secondary patenting is equally distributed over the lifetime of the first generation product and not cumulated towards its end.[217] It thus does not seem that easy to revitalize protection from a patent law perspective.

The EU Commission's concerns may be grounded in a policy perspective: Issues may arise in cases where follow-on innovations do not add (significant) benefits to patients over existing pharmaceutical therapies, but do meet patentability as well as comfortable pricing/reimbursement criteria.[218] In such cases, originators are granted 'fresh' exclusive rights for new but therapeutically non-superior drugs, which may allegedly be abused to shift demand to this second generation to maintain exclusivity. What is not considered by the sector inquiry though is that this scenario, which indeed may have negative social welfare implications, is not the standard but the exceptional case: Revitalizing exclusivity with a follow-on innovation is far from being a trivial exercise for an originator due to three important hurdles:

First, the follow-on innovation needs to meet patentability requirements of novelty and inventive step. The EU Commission indirectly criticizes that the EPO would grant patents on minor modifications too lightly, while generic companies have commented that EPO would overlook prior art and apply a rather loose 'inventive step' definition. Although one could argue whether too many weak patents are granted, a patent still must be analyzed

214 See supra note 10 at p. 51 and p. 100 and p. 509.
215 See supra note 10 at p. 164.
216 See supra note 59 at p. 37 referring to supra note 10 at § 1014, § 1016 as well as § 427, § 448 and § 473.
217 See supra note 10 at § 449, figure 55.
218 More effective therapeutic action is not assessed but alien to patent law, see supra note 10 at p. 100.

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under the presumption that the invention has deserved it.[219] A granted patent per definition is an invention contributing to (medical) progress and thus deserves time-limited exclusionary rights, although the direct and immediate value to patients may be low. The *Actavis v Merck* decision in the UK for example has confirmed that dosage requirements are patentable even if the associated medical indication is in the prior art.[220] Leveraging other protection schemes beyond patents provides even fewer opportunities: Data exclusivity requires long and expensive new clinical trials. Without those, most product changes from first to second generation would fall under the marketing authorization of the first generation product.[221]

Secondly, European national pricing and reimbursement systems normally consider therapeutic benefits vis-à-vis therapeutic costs (i.e. drug prices) – often referred to as the 'fifth hurdle to market access'. Consequently, already at the beginning of this century, the days were gone "(*if, indeed, they ever existed) when pharmaceutical pricing was a case of thinking of a number and doubling it."*[222] Today, a patented follow-on innovation therefore is evaluated from both a cost and benefit perspective. If this cost-benefit profile is not superior to existing substitutes (i.e. also to the originator's own first generation product), this may lead to no or unfavorably low reimbursement.

Third, even if the follow-on product is patentable and receives reimbursement status, the existing demand for the first generation product still has to be shifted to the second generation product. This often requires immense marketing and sales efforts due to information asymmetries between originators and the physician. Thereby again, therapeutic and pricing attributes compete with comparable substitutes (i.e. the originator's own established first generation product, post-LOE generic versions of this product and eventually even existing alternative innovative therapies by competing originators). It would be naïve to assume that all successful demand shifts in the past were realized without any favorable cost-benefit arguments.

219 See supra note 10 at p. 100 and pp. 449-450.
220 See Actavis UK Ltd v. Merck & Co Inc, 2008 EWCA Civ 444, 2008 R.P.C. 26.
221 See supra note 10 at p. 358.
222 Neil Turner, Containing global pharmaceutical costs: supply versus demand, The Pharma Letter (Oct. 20, 2000) available at http://www.thepharmaletter.com/file/37084/containing-global-pharmaceutical-costs-supply-versus-demand-by-neil-turner.html.

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Successfully maintaining revenues and profitability using follow-on innovations is therefore likely to be deserved if it really can be achieved by an originator. A starting point for limiting such behavior via competition law and proving abusive behavior lies more in unfair commercial practices of 'pushing' the second generation into the market rather than in IP or patent related aspects. Where marketing and sales practices are clean from fraud or any unprofessional behavior, e.g. do not include messages intended to denigrate generic products without objective arguments, originators are likely to be in safe harbors.[223]

The discretionary power of the EU Commission may thus focus their investigations rather on other identified conducts. Introducing restrictions for exclusivities of follow-on innovations could result in much lower incentives to innovation, which everyone agrees would be a 'false-positive', i.e. an intervention resulting into negative (dynamic) welfare effects.[224] *Arrow* however already suggested in the early 1970ies, that firms with less monopoly power have a higher incentive to behave in a dynamic and inventive manner compared to the ones with a dominant position.[225] Consequently, although the risk of a false-positive scenario is likely to hinder the EU Commission to strongly intervene in this area, there are also 'pro generic' arguments, which may be well received by legislators with a general 'evergreening' concern in mind.

4.2.3.2 Authorized Generic Entry and Dispute Settlement Agreements

Chapter 4.2.2.2. has shown that patent disputes and litigation are a frequently observable pattern and an integral part of generic defense strategies. Such litigation is either concluded by a final court decision, or settled with an *inter partes* agreement. The sector inquiry has raised strong concerns about the settlement practice of originators and generics, alleging that such deals may constitute restrictive business practices prohibited by Art. 101 TFEU. *Priddis* and *Constantine* observe that the final report *"calls into question nearly any circumstance in which patent litigation is settled"*[226]

223 See supra note 9 at p. 590.
224 See Id.
225 See Kenneth J. Arrow, Economic Welfare and the Allocation of Resources for Invention, in The Rate and Direction of Inventive Activity: Economic and Social Factors 609, 609-626 (Harold M. Groves ed., 1962).
226 See supra note 12 at p. 31.

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between an originator patent holder and an allegedly infringing generic competitor in its effort to enter the market. Special concerns are articulated where a settlement agreement involves a value transfer, also known as reverse payment, from the originator to the generic company in exchange for refraining from invalidating the patent and entering the market prior to formal patent expiry.[227] The final report does however not provide a clear legal assessment which could serve as the basis for future guidance to avoid anticompetitive allegations.[228]

From an economic perspective, settlement agreements with the potential to delay generic market entry are related to information asymmetries and the principle-agent dilemma as described in chapter 3.2.2:[229] Disputing parties form independent opinions about whether static competition is likely to be initiated prior to LOE due to patent invalidity. They typically have diverging perceptions about the strength of the underlying patent and thus about the win probability of the case.[230] A settlement agreement therefore often is the (subjectively) better outcome for both parties as it reduces uncertainty: The originator is able to maintain its exclusive rights until LOE while the generic company receives parts of the profits instead of maybe losing the case and getting nothing. Consequently, the value of such an agreement for the parties involved is especially high in situations where the originator patent holder believes to hold a weak patent likely to be invalidated, while the generic patent challenger expects the patent to be stronger. The alternative to settling the case for the generic competitor would not only be more risky, but also shows characteristics of a public good: The generic competitor could not (fully) appropriate all benefit from an invalidation success, as this would clear the way also for any other generic company.

A settlement agreement compensating the generic for a delay in its entry and the maintenance of a weak patent right, which could have otherwise been invalidated, may therefore not extend the formal but very well the effective exclusionary power of that weak patent.[231] Whether such agreement would come at welfare loss to the public thus depends on the weakness

227 See e.g. supra note 10 at § 1573.
228 See supra note 10 at § 1573.
229 See also supra note 73 at p. 11.
230 A Patent holder may know more about the weaknesses and invalidation probability of its right while attacking parties may tend to overestimate its strength.
231 See supra note 10 at pp.456-457 (considering this issue as eliminating price competition).

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of the patent, which the agreement itself avoids to conclusively assess. As former Competition DG Commissioner *Kroes* has put it, pharmaceutical patent settlements are agreed *inter partes "without the most effected [sic] stakeholders being present during the […] negotiations, namely the consumer or the health schemes representing their interests."*[232]

Concerns and reasoning of the EU Commission seems to be inspired by the U.S. Federal Trade Commission (FTC), where the issue has been highly disputed already for years.[233] The U.S. situation is however much more concerning due to a specific regulatory issue: The U.S. Hatch-Waxman Act allows generics to file an Abbreviated New Drug Application (ANDA) including a 'paragraph IV' certification, which constitutes an 'artificial' act of infringement under 35 U.S.C. § 271 (e) (2). By establishing jurisdiction in federal courts, this automatically triggers a validity/infringement law suit. Thereby, the U.S. system facilitates settlement agreements as it has established a solution to the public good problem described above: Generic competitors are incentivized to invalidate patents early as the first ANDA filer winning the subsequent law suit receives generic exclusivity of 180 days according to 21 U.S.C. § 355. In the US, this has led to various antitrust investigations, such as the deal associated with *Bayer Healthcare's* blockbuster product *Cipro®,* which included a total value transfer to *Barr Pharmaceuticals* of almost 398 million US$.[234] The FTC estimates that prohibiting such agreements could generate cost savings of 12 billion US$ for the federal budget over a period of 10 years. In contrast to this, the European situation seems much less severe: The sector inquiry only lists 45 agreements (or only 8% of all disputes) within the period from 2000 to 2007, of which only 23 involved a value transfer. The consolidated value of transfer payments from all agreements amounts to 200 million EUR – almost half of what a single case in the U.S. (i.e. Cipro®) had produced.[235]

Agreements in general however are an expression of the doctrine of freedom of contracts between two parties, which does nonetheless legitimate such a contract to restrict competition.[236] In addition, settlements are just an alter-

232 Press conference at the EU Commission (July 8, 2009) quoted according to supra note 12 at footnote 15.
233 See supra note 12 at p. 31.
234 See In re Ciprofloxacin Hydrochloride Antitrust Litigation 363 F. Supp. 2d 514 (E.D.N.Y. 2005) and 261 F. Supp. 2d 188 (E.D.N.Y. 2003).
235 See supra note 10 at p. 208 and supra note 68 at p. 18.
236 See supra note 68 at p. 24.

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native to achieve the originator patent holder's legitimate right to exclude competitors from profiting from its invention. But this also does not legitimate such conduct from being excluded from competition law scrutiny.[237] Most importantly, the economic bargaining function of such a deal can be regarded as a market-approach to reduce existing information asymmetries (similarly to license contract negotiations), which generally facilitate rather than restrict economically efficient solutions. *Inter alia*, procompetitive effects can be amplified in cases where agreements include 'early entry' opportunities for the generic competitor. In such constellations, authorized generics may enter the market based on an (exclusive) license, even months prior to LOE.[238] This produces welfare effects for patients, who can enjoy access to lower-priced drugs earlier, but also gives the 'preferred' generic a head start vis-à-vis other generic competitors in a temporary duopolistic setup together with the originator. It thereby may shield some market share from switching to other generic companies which may consider coming in post LOE and thereby reduces market attractiveness for further generic entry, which both parties benefit from.[239] Such 'side deals' can therefore also constitute a very effective 'buffer' to alleviate the pain from the inescapable LOE.[240]

According to the EU Commission – similarly to the U.S. FTC –, the role of value transfer in rendering a settlement agreement restrictive is especially important. The sector inquiry seems to imply that the size of value transfer may serve as a proxy for the weakness of the underlying patent and thus anticompetitive behavior. *Leibowitz* of the U.S. FTC goes even one step further: He argues, that value transfers do not only allow the parties of the agreement to share consumer wealth that would have resulted from lower prices following static competition,[241] but that such agreements would also lower dynamic competition: High value transfers by originators could have been invested into R&D instead of paying off generic competition.[242] In

237 See supra note 10 at p. 225 and p. 262 as well as supra note 78 at p. 12.
238 See supra note 10 at p. 89, § 236.
239 Compare supra note 10 at p. 297 with supra note 73 at p. 11.
240 See supra note 12 at p.31.
241 See supra note 10 at pp. 456-457.
242 See supra note 68 at p. 23.

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other words, originators would *"most likely [...] pay-off generic competitors when they have not innovated."*[243]

As parties buy off each other's litigation risk, any benefits granted in that course could basically be regarded as a value transfer – including the mere reimbursement of litigation expenses by the originator.[244] A license granted by an originator to its generic competitor as the result of a court settlement could, although having procompetitive effects as described above, also fall into the category of value transfer. In contrast, large cash payments may just signal the commercial importance of the underlying product and not necessarily the weakness of the patent right which it protects: As in the case of *Cipro®*, the value transfer was extraordinarily large, but the patent was evidentially proven rock-solid by two subsequent successful defenses against generic's invalidation attempts.[245] Value transfers in settlement agreements may thus occur not due to collusive intent, but risk adverse behavior of the originator: According to economists *Shapiro* and *Lemly,* every time a patent holder attempts to enforce its exclusionary power there is uncertainty and some sort of invalidation risk involved. This 'probabilistic patent theory' thus regards every patent to be 'a little bit invalid', as every patent would be a 'fuzzy' property right.[246] It thus seems evident how dangerous such a broad accusation is, when only focused on value transfer.

As an alternative, some authors, both in Europe and the US, have called for anticipating or 'second guessing' patent validity to determine anticompetitive effects in course of a competition law allegation of a settlement agreement.[247] Although this may theoretically be a clear cut solution to determine anticompetitive effects, it practically is an extremely complex issue in pharmaceuticals, which would require the expertise and experience of other

243 Jon Leibowitz, Chairman, U.S. Federal Trade Commission, speech at the Center for American Progress: 'Pay-for-delay' Settlements in the Pharmaceutical Industry: How Congress Can Stop Anticompetitive Conduct, Protect Consumers' Wallets, and Help Pay for health Care Reform (The $35 billion solution) (Jun. 23, 2009) (available at http://www.ftc.gov/speeches/leibowitz/090623payfordelayspeech.pdf).

244 See supra note 68 at p.15. and supra note 14 at p. 435 and supra note 12 at p.31.

245 Four generic companies filed ANDAs in subsequent years, i.e. Ranbaxy, Mylan, Schein and Carlsbad. See supra note 234.

246 See supra note 22 and Mark A. Lemley & Carl Shapiro, Probablistic Patents, 19 J. ECON. PERSP. 75 (2005).

247 For Europe, see supra note 73 pp. 11-12; for the U.S. see Asim Bhansali, Reverse-Payment Settlements After the Federal Circuit's in Re: Ciprofloxacin Decision, in Patent Law Institute 205, 211 (3rd annual patent law institute 2009).

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specialized jurisdictions.[248] Moreover, national member states' courts have already exclusive jurisdiction for invalidity cases according to Art. 22.4 of the *Brussels Regulation* 2001/44/EC.

With respect to the current state of EU competition law, patent settlement agreements may on the one hand be easier to render anticompetitive compared to other issues identified and discussed above: In contrast to the abuse of a dominant position under Art. 102 TFEU, Art. 101 TFEU cases have a longer history with the EU Commission as their logic can be compared to well known patterns of (price) cartels (see chapter 2.2.2.).[249] Moreover, any of such allegedly restrictive practices would be based on a formal contractual agreement. Anticompetitive effects or intent may therefore be proven more easily by authorities.[250] On the other hand, as the burden of proof for showing restrictive effects lies with the EU Commission, a strong case probably may only be brought forth, when based on evidence that the underlying patent was invalid, which is hardly possible without a company-internal 'smoking gun' document at hand.[251]

With respect to potential legislative change, *Schnichles,* the head of the EU Commission's Task Force running the inquiry, proposes to follow the U.S. FTC perspective as reflected in some currently discussed reform bills. According to these, any settlement agreement including a reverse payment would presumably be *per se* illegal, whereas the parties to the agreement may rebut this presumption by providing clear and convincing evidence of procompetitive outweighing anticompetitive effects.[252] Such a practice could however be in conflict with the treatment of IP settlements in EU Commission's legislation outlined in Regulation 772/2004/EC regarding the application of Art. 81.3 EC Treaty (today 101.3 TFEU) to categories of technology transfer agreements, to which the final report explicitly refers

248 See supra note 68 at p. 25.
249 See supra note 68 at p. 23.
250 See supra note 9 at p. 585.
251 See supra note 7.
252 See Eric J. Stock, Patent Settlement Developments: California Court Dismisses Challenge to Patent Settlement as Legislation Moves Forward in Congress, 14 Hogan & Hartson Life Sciences Competition & Antitrust Update 2, 2 (2009).

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as guidance.[253] *Gassner* however questions whether established legal opinions such as the *technology transfer* regulation could be applied at all in cases of patent settlements, as a resulting early entry agreement would follow different characteristics compared to traditional licensing agreements.[254]

One can conclude that out of the many issues discussed in the final report, patent settlement agreements have unambiguously reached the EU Commissions highest level of attention. Although the initial stage of the sector inquiry was very much focused on unilateral conduct under Art. 102 TFEU, the emphasis seems to have turned more towards restrictive agreements under Art. 101 TFEU due to easier proof finding associated with the difficulties in determining market dominance and abusive conducts under Art. 102 TFEU.[255] This was also confirmed by the first enforcement cases following the final report against *Lundbeck* and *Les Laboratoires Servier*.[256]

Although it may be harder for originators in the future to conclude favorable settlement agreements, the EU Commission admitted in the inquiry's final report to not yet be in a position of making policy recommendations.[257] It thus decided to gain more experience through a tailored monitoring exercise, the first annual report of which was published in July 2010, i.e. 18 months after its start.[258] This report unveiled that both originators and generics have already altered their behavior towards a much more risk-averse approach to patent settlements – most likely due to the strong allegations in the sector inquiry's final report and the above mentioned law suits initiated: Not only did the overall number of agreements with value transfer substantially decrease compared to the period analyzed in the sector inquiry,

253 Compare Commission Regulation 772/2004, 2004 O. J. (L 123) (EC) and supra note 10 at p. 508, § 1510 with Dominik Schnichels, The Application of European Competition Law to the Pharmaceutical Sector – Some Personal Thoughts 23 (Fordham Annual Conference on International Antitrust Law and Policy, discussion paper, Sept. 2009).

254 See supra note 73 at pp. 7-88.

255 See supra note 45 at p. 11.

256 See supra note 88.

257 Compare supra note 14 at p. 437 with supra note 10 at p. 458 and p. 524.

258 Compare Press Release IP/10/12, European Commission, Antitrust: Commission launches monitoring of patent settlements concluded between pharmaceutical companies (Jan. 12, 2010) with Press Release IP/10/887, European Commission, Antitrust: Commission welcomes decrease of potentially problematic patent settlements in EU pharma sector (Jul. 5, 2010).

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but also the monetary values of such transfers declined substantially. Beyond this, the monitoring report again does not provide any further guidance. It however stresses that settlement agreements without value transfer may nevertheless also infringe competition law: Either when they are based on deceptive conduct (following the *AstraZeneca* example) or when they impose restrictions on generics beyond the territorial scope of the patent.[259]

The lack of transparency for competition authorities to even detect 'problematic' agreements had also triggered the proposal to (re)introduce a notification system.[260] *Gassner* has argued that it seems unlikely that the EU Commission will provide more reliable guidelines on the issue, as this would voluntarily reduce its power to intervene.[261]

4.2.3.3 Intervention into Generic Marketing Authorization

IP related generic defense strategies can be used to not only extend the exclusionary effect of a patent within the legal regime of patent law, but also beyond that to independent bodies of law and regulation. By intervening into the marketing authorization process of a generic product, originators may trigger delaying or even blocking effects. They benefit from the suspensory feature, which an originator's appeal typically has on a generic marketing authorization process, such as frequently practiced not only by the German Federal Institute for Drugs and Medical Devices (BfArM).[262] According to the sector inquiry, originators frequently intervene into the generic product's approval process by arguing either lack of equivalence, raising safety and/or efficacy concerns or patent infringement. [263]

The pharmaceutical marketing authorization process is – as emphasized by the EU Commission – a bilateral procedure between the applicant and the regulatory authority, which generally is not designed to consider 3rd party interventions. This means that interventions into such proceedings cannot

259 See Richard Eccles, EU: European Commission Reports on the Monitoring of Patent Settlement Agreements (Online News Update, Bird & Bird, Jul. 28, 2010).
260 See supra note 10 at pp. 456-457 and supra note 14 at p. 435.
261 See supra note 73 at p. 12.
262 See supra note 78 at p. 10.
263 See supra note 10 at p. 863 and p. 874.

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be regarded *prima facie* as the exercise of a right.[264] Nevertheless, authorities would typically not simply ignore originator's articulated concerns where relevant to fulfill the authority's duty to ensure drug safety, efficacy and quality.[265] Launching an improved second-generation product and simultaneously unveiling new internal data to argue insufficient safety of the first-generation product and consequently also similar generic drugs, may be a potentially legal way to keep generics out.

Objectively more concerning are originator interventions with focus on patent-linkage arguments: Although generics *inter alia* require bioequivalence prove, authorities are not supposed to consider patent-related questions in the marketing authorization process according to Art. 8 of Directive 2001/83/EC. This is also true for questions related to patent infringement. Despite the patent's exclusionary right, such arguments are simply irrelevant in such decisions.[266] In this respect no U.S. FDA-like 'Orange Book' exists, which would provide a basis for infringement/invalidity discussions related to marketing authorization.

The same irrelevance exists with respect to patent-linkage interventions into national pricing and reimbursement decisions. Nevertheless, regulatory authorities of some EU member states still seem to be receptive for such arguments. *Postner* mentions the situation in Portugal as a good example.[267]

Similar to the EU Commission's perspective taken on blocking/defensive patents, also here a focus on the originator's 'primary' motivation behind such an intervention would be crucial to determine whether such an intervention is abusive under Art. 102 TFEU: Any *bona fide* concerns about a generic drug's safety or efficacy should indeed be raised even if that may block or delay generic entry. In contrast, pure intent to block or delay without substantive – or even irrelevant – arguments may be considered abusive under competition law. However, any intent-focused analysis immediately raises the problem of clear and convincing evidence, which seems to be very hard to generate for the EU Commission in any cases others than patent-linkage. The fact that safety or efficacy concerns are raised by the respective product's originator (and not any other 3rd party) should thereby not be easily interpreted by authorities as evidence against *bona fide* argu-

264 See supra note 9 at p.588.
265 See supra note 10 at § 1408.
266 See supra note 10 at p. 130 and § 874 and § 1408.
267 See supra note 78 at p. 10.

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ments: "*Originators are often best placed to identify those concerns, given its access to the relevant scientific research.*"[268]

Although the *AstraZeneca* case seems to be an extreme and too specific case likely to be replicated,[269] it seems clear that *"[m]isleading regulators to gain longer protection acts as a disincentive to innovate and is a serious infringement of EU competition rules"*.[270] Originators can expect that competition authorities will continue to investigate allegedly deceptive conduct. This may not only relate to the acquisition of SPCs, as in the *AstraZeneca* case, but also to deceptive exercise of other property-like rights, such as patents, in the cause of marketing authorization or pricing/reimbursement proceedings.[271]

Actions by the EU Commission to counter unjustified generic marketing authorization interventions by originators are likely to be focused on a stricter and more effective harmonized enforcement of the existing regulatory regime rather than individual competition law cases.[272] The sector inquiry already announced the willingness of the EU Commission to monitor such interventions more closely and to push national regulatory bodies to work on the transparency of such interventions.[273] Individual actions against anticompetitive pricing and reimbursement interventions are likely to be addressed more effectively by national member state competition authorities rather than by the EU Commission, as such systems are not (yet) harmonized across Europe.[274]

268 Supra note 12 at p. 31 Fn. 25.
269 See supra note 5 at p. 7.
270 See Ansgar Ohly, Geistiges Eigentum und Wettbewerbsrecht – Konflikt oder Symbiose, in Geistiges Eigentum und Gemeinfreiheit 47, 47 (Ansgar Ohly and Diethelm Kippel eds., 2007) (quoting former EU Commissioner Competition DG Neelie Kroes commenting the AstraZeneca decision).
271 For a general discussion see supra note 43 at p. 138.
272 See supra note 10 at §§ 1581-1606.
273 See supra note 10 at p. 491.
274 See supra note 9 at p. 588.

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5. Implications of Business Model Transformations

The EU Commission's findings of the sector inquiry constitute – as presented – historic observations and thus are mainly based on the traditional 'divide' of business models (see chapters 3.1.2. and 3.1.3.): On the one side large and vertically integrated multinational originators deliver chemical blockbuster drugs, while on the other side small incumbent generic companies challenge these big players post LOE by introducing similar products at much lower costs. It has been largely ignored by the sector inquiry that these clear boundaries and roles are subject to significant change as companies adapt their business models in Europe's dynamic and highly competitive pharmaceutical sector. Competition law will thus be confronted with more complex scenarios. Determining implications on IP related generic defense strategies therefore requires the consideration of these business model transformations.

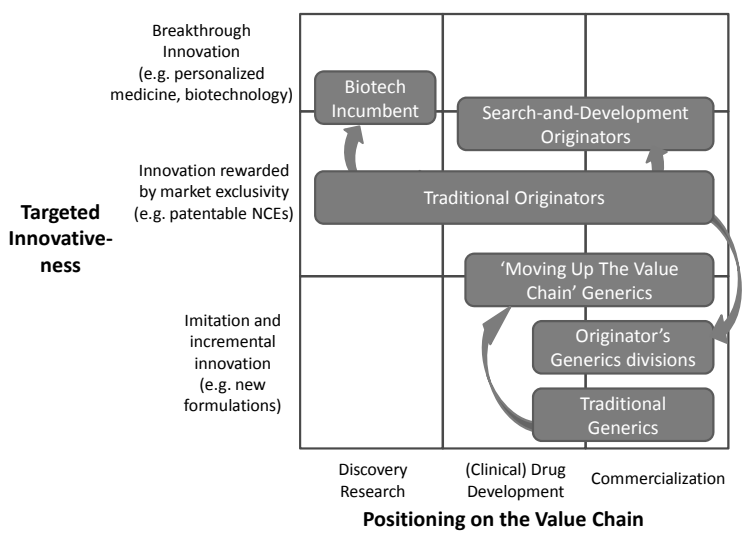

Figure 5:
Pharmaceutical business model transformations according to value chain positioning and targeted innovativeness.[275]

275 Own illustration.

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Originators as well as generics have found different strategic pathways to maintain or improve competitiveness in the marketplace:[276] While some apply a more focused approach, others substantially expand their business scope, either in scale or also in substance. Business models can thereby be differentiated according to the model's targeted innovativeness on the one hand and its position within the pharmaceutical value chain on the other hand, which is illustrated in figure 5. The two principle trends leading to those developments as well as their potential implications on generic defense strategies' limitations are discussed in the following chapters.

5.1. More Focused Business Models

5.1.1. Disentanglement of the Value Chain

Some originators, such as e.g. *Shire*, have established so called 'search and development' business models in which preclinical / early-stage discovery research is no longer performed in-house. Instead, attractive drug candidates are in-licensed from smaller research-focused companies, which look for partners to develop and commercialize their products. The source of innovation and thus its associated risk is 'disentangled' and shifted more towards those smaller entities. While those research companies focus on advanced science to provide the breakthrough innovation for successful future drugs, some multinational originators restrict themselves to bringing those candidates through clinical trials and develop marketable products. In the US, this development has already – since the beginning of this millennium – started to fragment the industry into such a two-tier system.[277] In extreme cases, originators even go one step further and not only externally source compounds, but also commercialize finished products via partners (e.g. contract sales forces) instead of using own resources.[278]

276 These observations are largely based on the author's own experience as a strategy consultant for the pharmaceutical industry.

277 See John P. Walsh et al., Research Tool Patenting and Licensing and Biomedical Innovation, in Patents in the Knowledge-Based Society 285 (Wesley M. Cohen and Stephen A. Merrill eds., National Academic Press 2003).

278 As an example, consider the Danish originator Nycomed prior to its acquisition of the pharmaceutical division of Germany's Altana: In this model, Nycomed restricted its in-house operations solely to drug development and 'virtualized' all other steps in the value chain through strategic partnerships.

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From an economic perspective, originators in such a disentangled model benefit from a lower risk profile, which however comes at the price of greater complexity, transaction costs and a higher dependency on the economic bargaining function of the patent system for striking effective licensing deals.[279] If more rather than less deal-making behavior will be required to bring an innovative drug on the market, patent thickets and blocking patents are likely to become an integral part of business strategies. It may also naturally bring the need for greater attention towards restrictive agreements according to Art. 101 TFEU.

Determining the abuse of a dominant position under Art. 102 TFEU in such a disentanglement scenario may also be affected: Originators may lose important arguments as large profits generated by patent exclusivities would be even less correlated with expected benefits from future R&D investments, as those are then made by different entities. In other words: As originators detach themselves from early stage research risk, they are also more vulnerable to competition law accusations related to market foreclosure via generic defense practices. A look to the US may even bring up similar discussions as seen in the post *eBay* antitrust decision,[280] where a patent holder not practicing the invention (itself) may not even be granted a permanent injunction against an infringer anymore.

5.1.2. Product Portfolio Shift Towards 'Nichebuster'

In addition to the separation of business activities one can observe originators shifting away from diseases with a large homogenous prevalence ('blockbusters') more towards niche market products and specialty pharmaceuticals ('nichebusters'). Although such segments have much smaller patient populations, competitive pressure from substitutability is consequentially also lower. Originators have acknowledged that even small patient pools can be economically attractive through high prices and reimbursement rates as well as faster, more effective development and approval procedures. Being able to bring a first-in-class therapy on the market is therefore more likely and creating a portfolio of therapies can help to spread

279 See supra note 10 at p. 99 (acknowledging the bargaining function of the patent system).

280 See eBay Inc. and Half.com v. MercExchange L.L.C., 74 U.S.L.W. 4248 (2006).

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the costs of promotion.[281] Good examples are rare and orphan diseases, which do enjoy special exclusivity (see chapter 2.1.2).

On the one hand, this trend is the result of a significant evolution in underlying scientific methods, where molecular biology and biochemistry have replaced traditional chemical science turning outputs towards a more 'personalized medicine' approach.[282] High-prevalence disease areas have either been largely exploited (e.g. antibiotics), have become extremely competitive (e.g. most of oncology) or scientific and technical hurdles have been prohibitive so far (e.g. neurodegeneration). On the other hand, this effect can also be regarded as a proactive generic defense strategy: Not only dynamic competition for innovation may be lower in such smaller and specialized markets, but also static competition. The smaller a market is, the lesser profits can be generated by a generic product, while generic development and commercialization costs remain largely unchanged (see drivers of generic entry discussed in chapter 3.3.1.). Consequently, although originator products in these new niche segments may not be totally unattractive for a generic competitor, they will however certainly enjoy a lower priority in market entry vis-à-vis large blockbuster products reaching their LOE.

Although the scientific developments, which have led to such trends, can be very closely associated with antibodies, genetic engineering and other biotechnological advancements, the sector inquiry admittedly neglected the issue of originator's defense against the so called biosimilars or biogenerics, i.e. imitations of such biotechnologically produced drugs.[283] Indeed, it is hard to predict implications as those product markets are still less established and immature. The majority of innovative biopharmaceuticals has not yet lost exclusivity. Today, less than 20 biosimilars are authorized for marketing in Europe. Nevertheless, considering the importance of this segment in the future as well as originator company's efforts to move away from the 'blockbuster' business model,[284] potential limitations for defense strategies should be understood in advance.[285] Unfortunately, many questions remain unanswered today, starting with fundamental issues such as

281 See Simon Goodall et al., Capitalizing on the Crisis – New Ways to Create Value in Biopharma 3, BCG Focus (The Boston Consulting Group 2009).
282 See supra note 10 at p. 471 (announcing to react with the 'EU pharmaceutical framework for the 21st century').
283 See supra note 10 at p. 24.
284 See supra note 78 at pp. 4-5.
285 See supra note 10 at p.24 & p.28 & p.34.

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how the relevant market would be defined to determine market dominance of a biopharmaceutical originator in competition with biogenerics.[286]

5.2. Broader Business Models: Scaling and Convergence

As an alternative to more focus, some players pursue transformations which rather broaden their activities:

5.2.1. Horizontal Scalability

Predominantly US-based originator companies, such as *Pfizer*, have continued to strengthen their fully integrated business models through large acquisitions of comparable firms (see chapter 3.1.2). Strengthening customer relationships, reinforcing product brands and continuing to set sights on blockbuster drugs targeting the primary-care segment can be regarded as a 'volume player' model: An attempt to continue the traditional approach with a larger scale and improved capabilities rather than a business model shift.[287]

In the competing generic segment, similarities can be observed: Recent tenders by hospitals and rebate negotiations of big health insurance companies have made generics' profit margins shrink further: In Germany for example, sometimes up to approximately 50 generic companies compete for the same molecule in one tender bid.[288] As a consequence, major generic players, such as Israel's *Teva Pharmaceuticals,* have begun to aggressively grow their business via acquisitions to benefit from the advantages of critical mass, such as increased bargaining power vis-à-vis large customer groups as well as cost degression in manufacturing and logistics. This has led to a substantial consolidation of the segment: While the global market

286 The AstraZeneca approach in defining the relevant market relied on the ATC structure, which is obviously not possible for large biological molecules.

287 Compare supra note 281 at p. 3 with supra note 10 at p.35. The sector inquiry regards those acquisitions as a move towards biotechnology, whereas the acquired targets have mainly been similar traditional originator companies with some focus on biopharmaceutical R&D pipelines, as can be seen based on the announced efficiency gains through synergies.

288 See supra note 78 at p. 5.

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share of the four leading generic companies was approximately 35% in 1997, it increased to over 60% ten years later.[289]

The strong growth of individual generic players may – in extreme cases – lead to a reverse scenario in terms of scale and market dominance: While a fragmented number of small research-focused entities develop innovation, large multinational generic powerhouses commercially exploit established products. Under such a situation, an originator's market dominance according to Art. 102 TFEU may be more difficult to satisfy, which would allow greater freedom to maneuver in the marketplace. In contrast, some of the discussed generic defense practices may fire back at originators in such a scenario: As building, clearing and litigating patent portfolios cost substantial money and resources, large generic players may in the future be in the powerful position to use similar weapons against smaller research-driven firms.

5.2.2. Business Model Convergence

An originator growing in scale may maintain its traditional business model as discussed above, but may also modify it by participating in the generic segment itself. Companies such as e.g. *Sanofi-Aventis*, have substantially invested into building own global generic divisions to participate in the attractive future growth rates of that business, while accepting a dilution of their ROIC. Moreover, access to and penetration of attractive emerging markets many be facilitated by lower-priced generic products.[290] Already in 2007, originator *Novartis'* own generic division *Sandoz* was the second largest global seller of generic pharmaceuticals with over 7 billion US$ in revenues.[291] Future acquisitions of generics by originators may therefore become a tough challenge for EU competition law's merger control.[292]

Also originator companies without own dedicated generic divisions often rely more on the profit contribution of established products than in the past.

289 See supra note 105.
290 See supra note 10 at p.34 as well as Hanspeter Spek, Executive Vice President Pharmaceutical Operations, Sanofi-Aventis, Presentation at the Pharmaceuticals Emerging Markets Conference (May 6, 2009).
291 See Andreas Rummelt, Chief Executive Officer, Sandoz, Presentation at the Merrill Lynch Generics Conference: Expanding the Boundaries of Generics (Dec. 1, 2008).
292 See supra note 182.

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While originators historically have frequently taken products off the market post LOE in order to focus attention on R&D efforts, the absence of R&D success and innovation has forced many companies to continue their commercialization in direct competition with generics.

While originators thus increasingly turn towards established and/or generic products to improve their risk/return ratio, the generic segment is characterized by an opposite trend: Some generic players have begun to put substantial efforts into 'moving up the value chain': They invest into own R&D operations to come up with (incremental) product innovations or substantial improvements themselves. Already in the period covered by the sector inquiry, generic companies invested on average 7% of their revenues into R&D and substantially increased their filing of secondary patents.[293] Own innovation and R&D investments are going to become especially relevant in the area of 'biosimilars', as biopharmaceuticals can only be successfully 'imitated' with much more effort and understanding of the underlying biological science of those large molecules: The German association of generic industries estimates average development costs per biosimilar of more than 200 million €.

When generic companies move from imitation towards innovation, originator companies need greater care in applying IP related generic defense strategies: The delay of market entry of a generic product which has more to offer than just lower prices may be regarded as prohibiting not only static but also dynamic competition in an abusive manner according to Art. 102 TFEU: If a generic product competes convincingly over safety or efficacy advantages, effects on the marketplace may be regarded as a matter of access to medical innovation. Competition authorities may thus have more arguments in finding anticompetitive effects from delay tactics, which will however depend on how broadly they will define 'innovation'.

293 See supra note 10 at p. 40 & p. 180.

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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.

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'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.

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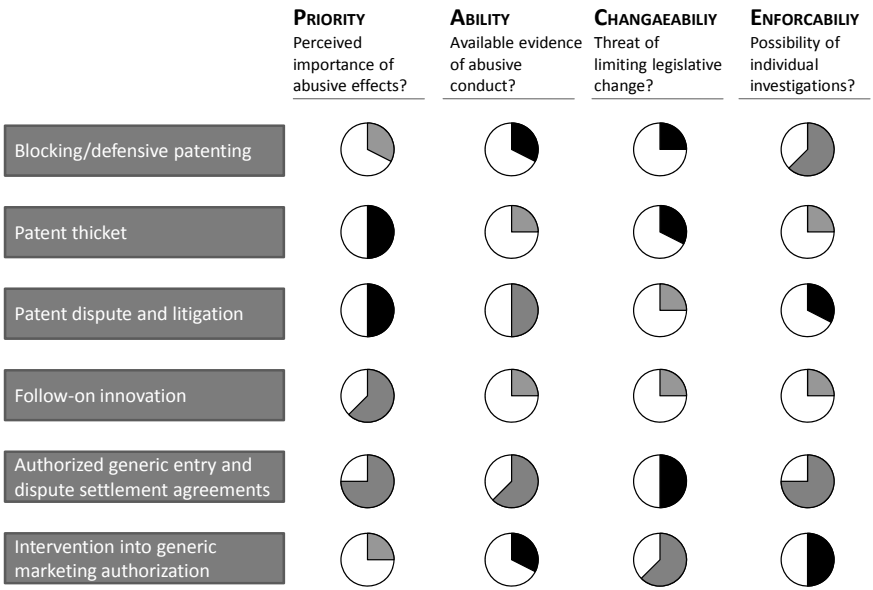

Harvey balls indicate relative threat level (greaterfilling = higher treat).
Red color indicate highest relative threat level per evaluation dimension; green color indicate lowest relative threat level per evaluation dimension.

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-

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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.

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