

**The Anticompetitive Misuse of Intellectual Property  
Rights in the European Pharmaceutical Sector**

**by**

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Thesis submitted for degree of

Doctor of Philosophy

University of East Anglia

UEA Law School

April 2014

Word count: 90,696

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## ABSTRACT

Pharmaceutical antitrust is currently a centre of attention for the European Commission, with one decision against *Lundbeck* and Statements of Objections in investigations against *Johnson & Johnson*, *Novartis*, and *Les Laboratoires Servier*. This thesis is the first to develop in detail a ‘European approach’ to pay for delay settlements and early entry agreements – two types of conduct identified by the European pharmaceutical sector inquiry. Although pay for delay settlements have received extensive antitrust scrutiny in the United States, one has to be cautious when drawing from this expertise, as the underlying regulatory regimes are fundamentally different in Europe and the US. This need for careful comparative analyses in pharmaceutical antitrust and the fact that similar conduct might have to be treated differently on both sides of the Atlantic is showcased by a case study of the General Court’s *AstraZeneca* judgment. The analysis shows that the General Court was correct to dismiss AstraZeneca’s claim that its conduct would not have led to antitrust scrutiny following the US Walker Process Doctrine, which in fact covers similar conduct. Additionally, the hypothetical application of the market definition in *AstraZeneca* to the market of anti-epileptic drugs highlights the difficulties that the European Commission might encounter in its future enforcement in the pharmaceutical sector.

Based on the different incentives for the parties of EU pay for delay settlements, a novel European theory of harm is developed for pay for delay settlements and early entry agreements, the latter posing significant anticompetitive potential in Europe. Based on this theory, pay for delay settlements are scrutinised under EU competition law and a novel “structured effects-based” test is proposed that is inspired by the recent *Actavis* judgment of the US Supreme Court. In terms of early entry agreements, this thesis is the first to apply EU competition law.

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## ACKNOWLEDGEMENTS

First and foremost I would like to thank Morten Hviid. He is not only a brilliant supervisor, but almost singled-handily responsible for my decision to apply for the doctoral research programme. Morten, you have not only inspired me but have also given me the belief and encouragement to do a PhD – something that I had never imagined before I came to UEA. I am also grateful for my second supervisor, Pinar Akman. Pinar, I cannot thank you enough for your detailed, thought-provoking comments and your advice. In the last 6 months of my PhD you went way beyond your call of duty by giving me detailed feedback on very short notice, while already working at Leeds University. I do not know what I would have done without your help. Overall, I can honestly say that I had an amazing supervisory team. I couldn't have asked for more.

I also would like to thank the ESRC Centre for Competition Policy and its members. The centre has not only provided me with office space and outstanding resources but also with an amazing academic environment. As a PhD candidate in the CCP, I have received a tremendous amount of support, advice and intellectual stimulation by its members – especially Michael Harker, Andreas Stephan, Christopher Wadlow, Peter Whelan and Sebastian Peyer.

I gratefully acknowledge the funding that I received from the Faculty of Social Science of the University of East Anglia and I am also grateful to the support of the UEA Law School; especially Duncan Sheehan and Peter Kunzlik, who have provided me with the time and space to finish this thesis during my first year as Lecturer at the law school.

I am also thankful to Pierre Larouche and the members of TILEC at Tilburg University, who have accepted me as a visiting researcher. During this period and with the exceptional support from Pierre, I have written a substantial part of my thesis.

I also want to thank Dave Reader, who is a true friend and helped me tremendously with the proof-reading of my thesis. Overall, this PhD would also not

have be possible without my friends here at UEA, who have kept me sane and ensured that I not only think about drugs, pharmaceutical companies, patents and antitrust. A special thanks to Matthias Neumann, Richard Deswarte and Richard Mills. I have always enjoyed our conversations over an “End of Week” pint. I hope there are many more to come.

I could also not have reached this point in my life without the support of my Mum and Dad who have always encouraged me to aim high. For your support, and love, I am truly grateful.

Finally and most importantly I would like to thank my best friend who happens to be my amazing wife and mother of our beautiful daughter. You are a star. You have given my life a whole new purpose. I do not know what I would have done without your love and unwavering support.

Norwich, April 2014

Sven Gallasch

## I. INTRODUCTION

### 1. Purpose of the thesis

This thesis explores the specific types of conduct engaged in by innovating pharmaceutical companies (brand companies) and generic pharmaceutical manufacturers (generic companies) who extend patent protection, or the monopolistic profits associated with patent protection, beyond the life of the intellectual property right. In particular, this thesis investigates pay for delay settlements and early entry agreements in the European pharmaceutical sector. Fundamentally, the aim of this thesis is to establish whether or not the European Commission can rely on the extensive expertise of the US authorities and courts with regard to pharmaceutical antitrust or if it has to develop its own approach to these types of conduct based on a European theory of harm. Before one can establish the need for a European approach to pharmaceutical antitrust, one has to address the following questions:

*What are the differences between pharmaceutical antitrust in Europe and the United States? Are the two regimes actually comparable? What factors do we have to consider if we, nevertheless, want to draw from the US expertise?*

These questions will be answered throughout this thesis, informing the development of a novel European theory of harm and providing an analysis of pay for delay settlements and early entry agreements in the context of European competition law. These analyses will include the proposal of a novel “structured effects-based” test for European pay for delay settlements and, for the first time, a detailed competition law analysis of early entry agreements in Europe.

### 2. Setting the scene

This section shall help the reader to appreciate, on the one hand, the importance of patent protection for brand companies in the pharmaceutical sector in general and, on the other hand, the issues that raise antitrust scrutiny towards the end of patent

protection. Finally, it identifies the status quo of the US and European antitrust enforcement in relation to pay for delay settlements, thereby alluding to the fundamental differences between the two regulatory regimes, which warrants cautious comparative legal analysis.

Pharmaceutical antitrust is an important yet complex field of competition policy. Its aim is to ensure that the consumer is provided with life-saving medicine priced at a competitive level. However, what makes the field of pharmaceutical antitrust so problematic is the highly regulated nature of the pharmaceutical sector and the fact that brand companies are heavily reliant on patent protection, more so than any other high-tech sector.<sup>1</sup> The importance of patent protection can be explained by the resource-intensive and time-consuming nature of the drug discovery process and the lengthy and highly regulated drug approval procedure.

New drugs are extremely expensive to develop. A number of economic studies have estimated the costs of research and development (R&D) for a new drug to be several hundred million US dollars,<sup>2</sup> with the highest estimate for a single drug being US\$1.8 billion.<sup>3</sup> These costs are extremely high for a number of reasons. The success rate for the development of new drugs is very low. Typically, less than 1 per cent of the molecules<sup>4</sup> discovered in pre-clinical tests enter the clinical trial stage,<sup>5</sup> and only 16 per cent of these molecules survive the process of

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<sup>1</sup> Henry Grabowski, 'Patents, innovation and access to new pharmaceuticals' (2002) 5 *Journal of International Economic Law* 849, 850.

<sup>2</sup> Joseph A DiMasi, Roland W Hansen and Henry G Grabowski, 'The price of innovation: new estimates of drug development costs' (2003) 22 *Journal of Health Economics* 151 (finding an estimated average out-of-pocket cost per new drug is US\$ 403 million (2000 dollars). Capitalizing out-of-pocket costs to the point of marketing approval at a real discount rate of 11% yields a total pre-approval cost estimate of US\$ 802 million (2000 dollars)); Christopher P Adams and V. van Brantner, 'Estimating The Cost Of New Drug Development: Is It Really \$802 Million?' (2006) 25 *Health Affairs* 420; Christopher P Adams and Vu van Brantner, 'Spending on new drug development' [2010] 19 *Health Economics* 130; Both studies replicate the estimates in the DiMasi study and come to similar findings of an average of US\$ 868 million with variations from US\$ 500 million to US\$ 2000 million.

<sup>3</sup> Steven M Paul and others, 'How to improve R&D productivity: the pharmaceutical industry's grand challenge' (2010) 9 *Nature Reviews Drug Discovery* 203, 205.

<sup>4</sup> The term molecules refers to the chemical compounds in a drug that cause the therapeutic effect in patients.

<sup>5</sup> Grabowski (n 1) 851.

human clinical trials and gain drug approval.<sup>6</sup> The R&D costs of these failed molecules, that will never reach the market, are thus a substantial part of the aforementioned estimates. In addition, the development of a new drug is very time-consuming. It has been estimated that the development takes, on average, 12 years from the initial discovery of a new molecule to the final market approval of the new drug.<sup>7</sup> By contrast, generic drugs are a lot easier and cheaper to develop, as the generic company does not have to undertake the same time-consuming R&D with the same low success rate as the brand company. Generic drug companies can rely on the clinical test results of the brand company, because the generic drug has to be chemically identical to the brand drug, otherwise known as ‘bioequivalence’.<sup>8</sup> This process normally takes a few years and will usually cost between US\$1-2 million.<sup>9</sup> Due to these significant cost and time differences, patent protection (which generally lasts for 20 years from the point of application) is vital for the brand company, as the generic company would otherwise have the ability to “free-ride” on the brand company’s innovation.<sup>10</sup>

Yet, in contrast to other sectors, the effective patent life in the pharmaceutical sector is a lot shorter. This is owing to the fact that pharmaceutical patents are applied for at the point of discovery of the relevant molecule prior to the clinical testing which, as noted above, can take up to 12 years.<sup>11</sup> Brand companies, therefore, have a significantly shorter period of time in which to recover the substantial R&D investment in a new drug, which also explains their

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<sup>6</sup> J. A DiMasi and others, ‘Trends in Risks Associated With New Drug Development: Success Rates for Investigational Drugs’ (2010) 87 *Clinical Pharmacology & Therapeutics* 272 (using a sample of all drug in the pipeline of the 50 largest pharmaceutical companies which entered into clinical testing in the period 1993-2004 through to 2009.)

<sup>7</sup> DiMasi, Hansen and Grabowski (n 2) 181. For a description of the development process of a new drug see Appendix sec. 1.1. (for the United States) and sec. 2.1. (for Europe).

<sup>8</sup> In relation to the European framework see Council Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use [2001] OJ L 311, Art. 10 (1) (the generic company does not have to provide the ‘*results of pre-clinical tests and of clinical trials if he can demonstrate that the medicinal product is a generic of a reference medicinal product which is or has been [already] authorised*’). For the similar regulation for the United States see 21 U.S.C. §355 (j)(2)(A).

<sup>9</sup> Grabowski (n 1) 852.

<sup>10</sup> *Ibid.* 851.

<sup>11</sup> Henry G Grabowski and Margaret Kyle, ‘Generic competition and market exclusivity periods in pharmaceuticals’ (2007) 28 *Managerial & Decision Economics* 491, 492.

incentive to extend the period of patent protection by as much as possible. A large proportion of the costs are incurred at the beginning of the development of the new drug, whereas the majority of the revenue is generated towards the end of the patent life, which has been estimated to be 9 to 14 years.<sup>12</sup> The apparent discrepancy between the time for development and the remaining period of effective patent life is to be explained by what is regarded as ‘patent restoration provisions’.<sup>13</sup> Most countries with brand companies have enacted such provisions to mitigate the loss of patent life caused by the time-consuming regulatory procedure for drug approval and to avoid a stifling effect on innovation.<sup>14</sup>

Notwithstanding this, brand companies – as profit-maximising corporations – attempt to extend the patent protection by as much as possible, particularly because of the amount of revenue that is potentially at stake. This is highlighted by a statement made by the CEO of Cephalon, a large US biopharmaceutical company, in relation to a settlement entered into with 4 generic companies:

*‘We were able to get six more years of patent protection. That’s \$4 billion in sales that no one expected.’<sup>15</sup>*

However, this gain in revenue goes beyond the gain envisaged by pharmaceutical patent policy, which is aimed at ensuring an adequate return for the brand company’s innovation. In the case of *Cephalon*, this additional revenue was achieved by a so-called *pay for delay* settlement in which the brand company pays-off the first generic entrant in order to keep them out of the market. In the United States, it is exactly this kind of pay for delay settlement that has raised significant antitrust concern for the Federal Trade Commission.

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<sup>12</sup> Joseph A DiMasi and Henry G Grabowski, ‘R&D costs and the return of new drug development: A review of the evidence’ in Patricia M Danzon and Sean Nicholson (eds), *The Oxford handbook of the economics of the biopharmaceutical industry* (Oxford University Press, Oxford, 2012) 36, 37; also Grabowski and Kyle (n 11).

<sup>13</sup> For a detailed description please see Appendix sec. 1.1.3 (for the United States) and sec. 2.1.3. (for Europe)

<sup>14</sup> Grabowski (n 1) 852.

<sup>15</sup> ‘FTC v. Cephalon, Inc. No. 08-cv-2141: Complaint for injunctive relief’ (13 February 2008) <<http://www.ftc.gov/enforcement/cases-proceedings/061-0182/cephalon-inc>>, 2.

In fact, the Federal Trade Commission (FTC) has estimated that such pay for delay settlements have deprived consumers in the United States of savings totalling *US\$3.5 billion* over the period of 2004 to 2009.<sup>16</sup>

The FTC has devoted significant time and resources to the research into pay for delay settlements and pharmaceutical antitrust more generally, resulting in an extensive body of research in the form of reports,<sup>17</sup> as well as significant expertise in terms of the FTC's advocacy efforts<sup>18</sup> and the investigations it has undertaken at its own initiative over the last decade.<sup>19</sup> Also, a substantial body of case law of conflicting opinions has been developed based on private enforcement initiatives.<sup>20</sup> Based on these conflicting opinions, a split between Circuit courts finally led to an appeal to the US Supreme Court that handed down its judgment on 17 June 2013.<sup>21</sup>

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<sup>16</sup> Federal Trade Commission, *Pay-for-Delay: How drug company pay-offs cost consumers billions* - A FTC staff study (2010) <<http://www.ftc.gov/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff>>.

<sup>17</sup> Federal Trade Commission, *Generic drug entry prior to patent expiration: A FTC study* (2002) <<http://www.ftc.gov/reports/generic-drug-entry-prior-patent-expiration-ftc-study>>; Federal Trade Commission, *To promote innovation: The proper balance of competition and patent law and policy*. A report by the Federal Trade Commission (2003) <<http://www.ftc.gov/os/2003/10/innovationrpt.pdf>>; Federal Trade Commission, *Authorized Generics: An interim report* (2009) <<http://www.ftc.gov/reports/authorized-generics-interim-report-federal-trade-commission>>; Federal Trade Commission, *Pay-for-Delay: How drug company pay-offs cost consumers billions* (n 16). Federal Trade Commission, *Authorized Generic Drugs: Short-Term Effects and Long-Term Impact* (2011) <<http://www.ftc.gov/reports/authorized-generic-drugs-short-term-effects-long-term-impact-report-federal-trade-commission>>.

<sup>18</sup> The Federal Trade Commission filed amicus curiae briefs in a number of cases: e.g. *In re Cardizem CD Antitrust Litigation* 332 F.3d 896 (6th Cir. 2003); *In re K-Dur Antitrust Litigation* 686 F. 3d 197 (3d Cir. 2012); *Federal Trade Commission v. Watson Pharmaceuticals Inc.* 677 F.3d 1298 (11th Cir. 2012); *In re Ciprofloxacin Hydrochloride Antitrust litigation* 544 f.3d 1323 (Fed. Cir. 2008), cert. denied, 129 S.Ct. 2828 (2009); *In re Tamoxifen Citrate Antitrust Litigation* 466 F.3d 187 (2nd Cir. 2005); *Valley Drug Co. v. Geneva Pharmaceuticals, Inc* 344 F.3d 1294, (11th Cir. 2003).

<sup>19</sup> *FTC v. Cephalon, Inc.* 551 F. Supp. 2d 21 (D.D.C. 2008); *Schering-Plough Corp. v. FTC* 402 F.3d 1056, (11th Cir. 2005).

<sup>20</sup> *Federal Trade Commission v. Watson Pharmaceuticals Inc.* 677 F.3d 1298 (11th Cir. 2012); *In re Ciprofloxacin Hydrochloride Antitrust litigation* 544 f.3d 1323 (Fed. Cir. 2008); *In re Tamoxifen Citrate Antitrust Litigation* 466 F.3d 187 (2nd Cir. 2005) all finding pay for delay settlements to be lawful and *In re K-Dur Antitrust Litigation* 686 F. 3d 197 (3d Cir. 2012) finding such settlements to be presumptively unlawful.

<sup>21</sup> A split circuit refers to the situation when a number of circuit courts have handed down diverging judgments over the same issue. Such a split circuit significantly increase the change for the US Supreme Court to grant writ certiorari (appeal for judicial review), as it has happened in *FTC v. Actavis* 133 S.Ct. 2223 (2013).

In addition to the FTC's efforts in respect of pay for delay settlements, it has filed administrative complaints against pharmaceutical companies that have abused the regulatory system for the approval of drugs.<sup>22</sup> In the matter against *Bristol-Myers Squibb*, for example, the FTC issued a complaint against the company for the violation of section 5 of the Federal Trade Commission Act, asserting that the company had wrongfully acquired a patent by providing misleading information to the US Patent and Trademark Office. In doing so, Bristol-Myers Squibb was able to delay timely entry of a generic version of the drug BuSpar because of the peculiarities of the regulatory system for generic drug approval in the United States.<sup>23</sup>

It is exactly these types of conduct that should attract antitrust scrutiny, where the brand company unilaterally or in a concerted effort with the generic company, attempts to extend its monopolistic profits beyond the life of the patent.

Despite the fact that, so far, all of the examples and enforcement initiatives provided are US-based, pharmaceutical antitrust is no longer unique to the United States. For a number of years, the pharmaceutical sector has been a central point of focus for the European Commission and has led to a significant amount of competition law enforcement activities. In 2005, for instance, the European Commission issued a key decision against AstraZeneca. This found that the company abused its dominant position by providing misleading information to patent offices, resulting in the granting of patent extensions of which the company would not have been entitled to.<sup>24</sup> On appeal, the General Court and the Court of Justice had – for the first time – an opportunity to address the misuse of intellectual

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<sup>22</sup> Federal Trade Commission, Administrative complaint in the matter of Bristol-Myers Squibb. FTC file No.0110046. <<http://www.ftc.gov/enforcement/cases-proceedings/0110046/bristolmyers-squibb-company-matter%3e.%20>>

<sup>23</sup> Federal Trade Commission, *Analysis to aid public comment: In the Matter of Bristol-Myers Squibb Company File Nos. 001 0221, 011 0046, and 021 0181* (2003) <<http://www.ftc.gov/os/2003/03/bristolmyersanalysis.htm>>.

<sup>24</sup> *AstraZeneca (Case COMP/A. 37.507/F3) Commission Decision 2006/857/EC*, [2005] OJ L 332.



property rights in the context of competition law and policy, largely upholding the European Commission's decision in 2010 and 2012 respectively.<sup>25</sup>

In 2008, the European Commission also launched its pharmaceutical sector inquiry to investigate an apparent lack of competition in the sector. On 8 July 2009, the final report was published which found that market entry for generic drugs was being delayed and that there had been a decline in the number of novel medicines reaching the market. On the day of the publication, it was stated by the then Commissioner for Competition, Neelie Kroes, that it was now clear what was wrong with the sector and that the time had come to act, emphasising that the Commission would not hesitate to apply the antitrust rules to types of conduct that delay generic entry in an anticompetitive way.<sup>26</sup> The final report was followed by four annual monitoring reports,<sup>27</sup> in addition to the launch of a number of formal proceedings against pharmaceutical companies suspected of attempting to delay the entry of generic drugs into the relevant pharmaceutical market.

On 7 January 2010, an investigation was opened into the Swedish pharmaceutical brand company Lundbeck and a number of generic drug makers in relation to the delayed entry of generic versions of the anti-depressant drug

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<sup>25</sup> Case T-321/05 *AstraZeneca v European Commission* (2010) ECR 00; upheld by Case C-457/10 P *AstraZeneca v European Commission* (ECJ, 6 December 2012).

<sup>26</sup> European Commission, *Antitrust: shortcomings in pharmaceutical sector require further action* (Brussels, 8 July 2009) <[http://europa.eu/rapid/press-release\\_IP-09-1098\\_en.htm](http://europa.eu/rapid/press-release_IP-09-1098_en.htm)>.

<sup>27</sup> These monitoring exercises collected information about the patent settlements concluded between brand companies and generic companies during the respective monitoring periods and analysed them for their potential delay of generic entry including a value transfer to the generic company. The first report saw a decrease in problematic settlements from 22% (45 settlements) during the sector inquiry to 10% (9 settlements). European Commission, *1st Report on the Monitoring of Patent Settlements (period: mid 2008 - end 2009)* (2010) <[http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/patent\\_settlements\\_report1.pdf](http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/patent_settlements_report1.pdf)>; The second monitoring exercise reported a further reduction to 3% (3 settlements) European Commission, *2nd Report on the Monitoring of Patent Settlements (period: January-December 2010)* (2011) <[http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/patent\\_settlements\\_report2.pdf](http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/patent_settlements_report2.pdf)>; while the last two exercises recorded an increase to 11% (11 settlements) and 7% (13 settlements) respectively. European Commission, *3rd Report on the Monitoring of Patent Settlements (period: January-December 2011)* (2012) <[http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/patent\\_settlements\\_report3\\_en.pdf](http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/patent_settlements_report3_en.pdf)>; European Commission, *4th Report on the Monitoring of Patent Settlements (period: January-December 2012)* (2013) <[http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/patent\\_settlements\\_report4\\_en.pdf](http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/patent_settlements_report4_en.pdf)>.

citalopram.<sup>28</sup> This investigation recently led the European Commission to issue its first decision against pharmaceutical brand and generic companies in relation to European pay for delay settlements, imposing fines totalling €146 million.<sup>29</sup> In a similar investigation, Johnson & Johnson and Novartis were fined €16 million for delaying the entry of a generic version of the pain-killer fentanyl in the Netherlands.<sup>30</sup> In another major case, Les Laboratoires Servier and a number of generic drug makers were issued with a statement of objections alleging the delay of entry for the generic version of the cardiovascular drug perindopril on 30 July 2012.<sup>31</sup>

However, European enforcement activities cannot conceal the fact that the authorities' expertise and academic thinking in pharmaceutical antitrust is trailing behind the United States. Describing the situation in the United States, one commentator as pointed out:

*'Much ink has been spilled out on the topic of [pay for delay] settlement arrangements and their antitrust implications'*<sup>32</sup>

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<sup>28</sup> European Commission, *Antitrust: Commission opens formal proceedings against pharmaceutical company Lundbeck* (Brussels, 7 January 2010) <[http://europa.eu/rapid/press-release\\_IP-10-8\\_en.htm](http://europa.eu/rapid/press-release_IP-10-8_en.htm)>.

<sup>29</sup> European Commission, *Antitrust: Commission fines Lundbeck and other pharma companies for delaying market entry of generic medicines* (Brussels, 19 June 2013) <[http://europa.eu/rapid/press-release\\_IP-13-563\\_en.htm](http://europa.eu/rapid/press-release_IP-13-563_en.htm)>.

<sup>30</sup> European Commission, *Antitrust: Commission fines Johnson & Johnson and Novartis € 16 million for delaying market entry of generic pain-killer fentanyl* (Brussels, 10 December 2013) <[http://europa.eu/rapid/press-release\\_IP-13-1233\\_en.htm](http://europa.eu/rapid/press-release_IP-13-1233_en.htm)>.

<sup>31</sup> European Commission, *Antitrust: Commission sends Statement of Objections on perindopril to Servier and others* (Brussels, 30 July 2012) <[http://europa.eu/rapid/press-release\\_IP-12-835\\_en.htm](http://europa.eu/rapid/press-release_IP-12-835_en.htm)> At the time of submission of this thesis a final decision in this investigation was not yet issued.

<sup>32</sup> Thomas F Cotter, 'Antitrust Implications of Patent Settlements Involving Reverse Payments: Defending a Rebuttable Presumption of Illegality in Light of Some Recent Scholarship' (2003) 71 *Antitrust Law Journal* 1069, 1069; the dichotomy between the US courts is to a certain degree reflected in the academic literature. For example, Kevin D McDonald, 'Patent Settlements and Payments that Flow the "Wrong" Way: The Early History of a Bad Idea' (2002) 15 *Antitrust Health Care Chronicle* 2 (argues that pay for delay settlements should generally not be regarded as anticompetitive as long as they are within the scope of the patent, requiring genuine belief that the relevant patent is invalid); Daniel Crane, 'Ease over accuracy in assessing patent settlements' (2004) 88 *Minnesota Law Review* 689 (accepts the anticompetitive potential but argues for an *ex-ante* evaluation of the likelihood that the generic company would be excluded from the market if the case was finally adjudicated); Marc G Schildkraut, 'Patent-splitting settlements and the reverse payment fallacy' (2003) 71 *Antitrust Law Journal* 1033 (advocates for a non-interventionist approach because of the complexity of the process); Others are, however, in favour of illegality Thomas F Cotter, 'Refining the "Presumptive Illegality" Approach to Settlements of Patent Disputes Involving Reverse

Indeed, compared to the extensive discussion of the issue in the United States, academic discussion in Europe is limited or, rather, in its infancy. An early article by Murphy sets out some of the differences between the two regulatory systems and calls for the application of the “scope of the patent” test,<sup>33</sup> as was applied in the *Schering Plough* decision of the 11<sup>th</sup> Circuit.<sup>34</sup> Discussing the application of Art. 101 TFEU to pay for delay settlements, Marc van der Woude highlights the difficulties that arise from the fact that these kinds of settlements have not yet been addressed by the European courts and, thus, explores the potential to apply related case law regarding trademark delimitation agreements and no-challenge clauses.<sup>35</sup> The only recent detailed analysis of pay for delay settlements under EU competition law strongly advocates for a case-by-case analysis for proving anticompetitive effects because of the probabilistic nature of patent settlements.<sup>36</sup> However, at the same time, the analysis suggests that the European Commission would need to distance itself from an effects-based analysis, which it proclaimed in its pharmaceutical sector inquiry,<sup>37</sup> and rather would have to regard these settlements as restrictions by object in order to have success. Since then, the application of EU

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Payments: A Commentary on Hovenkamp, Janis & Lemley’ (2003) 87 *Minnesota Law Review* 1789 (determines illegality based on the probability of success in the patent law suit); Herbert J Hovenkamp, Mark D Janis and Mark A Lemley, ‘Anticompetitive Settlement of Intellectual Property Disputes’ (2003) 87 *Minnesota Law Review* 1719 (suggest a rebuttable presumption based on the patent holder’s anticipated litigation costs) Michael A Carrier, ‘Unsettling drug patent settlements: A framework for presumptive illegality’ (2009) 108 *Michigan Law Review* 37 (bases the decision on the reasonableness of the payment from the brand company to the generic company); C. S Hemphill, ‘An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition’ (2009) 109 *Columbia Law Review* 645 (argues for a presumption because of the growing complexity of these settlements); Others again offer an alternative route through legislative change C. S Hemphill, ‘Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem’ (2006) 81 *New York University Law Review* 1553; Michael A Carrier, ‘Solving the Drug Settlement Problem: The Legislative Approach’ (2009) 41 *Rutgers Law Journal* 83; C. S Hemphill and Mark A Lemley, ‘Earning Exclusivity: Generic Drug Incentives and the Hatch-Waxman Act’ (2011) 77 *Antitrust Law Journal* 947;

<sup>33</sup> Mark W Murphy, ‘Red flag or red herring? Reverse payments and the settlement of pharmaceutical patent litigation’ (2008) 4 *European Competition Journal* 541.

<sup>34</sup> *Schering-Plough Corp. v. FTC* 402 F.3d 1056, (11th Cir. 2005).

<sup>35</sup> Mark van der Woude, ‘Patent Settlements and Reverse Payments Under EU Law’ (2009) 5 *Competition Policy International* 182.

<sup>36</sup> Pat Treacy and Sophie Lawrance, ‘Intellectual property rights and out of court settlements’ in Steven D Anderman and Ariel Ezrachi (eds), *Intellectual property and competition law: New frontiers* (Oxford University Press, Oxford, 2011).

<sup>37</sup> European Commission (n 26) para. 1575.

competition law to pay for delay settlements has not been discussed any further by means of a detailed legal analysis.

Given the comparatively limited enforcement expertise of the European Commission and the limited academic thinking in the field, one could be tempted to draw from the expertise and the academic advancement in the United States in order to address issues of pharmaceutical antitrust in Europe.

Yet, this thesis calls for caution when drawing from the wealth of experience of the United States in relation to pharmaceutical antitrust, because of fundamental differences between the pharmaceutical drug approval litigation in the United States and Europe. These differences are highlighted by the following brief discussion.<sup>38</sup>

In contrast to the relevant European authorities, the US Food and Drug Administration (FDA) does not only take factors such as safety, quality and efficacy into consideration during the generic drug approval process, but also economic factors such as the patent protection in relation to the relevant brand drug. This creates a so-called patent linkage in the US regulatory system with far-reaching consequences. This patent linkage, which has been introduced by the Hatch Waxman Act, allows the brand company to attack the generic drug application – which is filed before the relevant patents have expired – with a patent infringement lawsuit, leading to a delay of generic drug approval. In order to incentivise the generic entrant to nevertheless take the risk of applying for drug approval prior to the expiry of the brand company's relevant patents, the first generic company is granted a generic exclusivity of 180 days, after the patent dispute is resolved. Until the generic exclusivity period has elapsed, the FDA is not allowed to accept any further generic drug applications for the litigated drug. It is these peculiarities in the regulatory drug approval process in the United States that open the door for procedural misuse by the involved parties. Instead of litigating, the parties resolve their dispute by means of settlement and stipulate the date of generic market entry,

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<sup>38</sup> This brief description does not include all the details of the respective regulatory regimes. It shall rather give the reader a general feel for the situation and set the overall scene. The detailed discussion of the differences between the US and EU regime takes place in chapter III.

which then triggers the generic companies exclusivity period of 180 days. The parties are therefore able to foreclose the relevant pharmaceutical market, as the FDA is not allowed to accept any further generic applications, thus acting as a gate keeper.

The European framework, however, lacks such a patent linkage. Brand companies can also attack generic companies by means of a patent infringement lawsuit, if they enter the market prior to patent expiry. However, the brand company cannot foreclose the market by paying off a single generic entrant, as economic factors such as patent protection are not considered during the drug approval process. Generic companies might therefore risk patent infringement litigation prior to the brand company's patent expiry, but they are not prevented from entering the market by the drug approval regulation in Europe, even if the brand company has already paid-off one or more of the generic competitors. Foreclosure is, thus, not achievable by the same means as in the United States.

This brief description of the fundamental differences between the two regulatory regimes already highlights the importance of the questions posed at the outset of this introduction and hints at the need to develop a European approach to pharmaceutical antitrust, particularly in relation to pay for delay settlements. It would be wrong to simply apply the US approach to pay for delay settlements in Europe, without having first conducted a detailed comparative legal analysis.

### **3. Originality**

Following the detailed comparative analysis of US and European regulatory framework, a European theory of harm for pay for delay settlements is devised, which accounts for the regulatory differences in Europe. This theory leads up to the analysis of these settlements under EU competition law and the development of a novel "structured effects-based" test. Inspired by the US Supreme Court's judgment in *FTC v Actavis*, the proposed test also circumvents the need to determine the validity of the relevant patent and the probability of success in patent litigation. The test does not, however, simply apply the rationale of the *Actavis* judgment, but rather adapts it to the peculiarities of the European pharmaceutical framework.

In addition to this novel European approach to pay for delay settlements, this thesis is also the first to develop a European theory of harm for so-called early entry agreements, which have also been identified by the European Commission in its sector inquiry.<sup>39</sup> Following this agreement between a brand company and a generic company, the generic company is allowed market entry prior to the expiry of the brand company's patents. In return for this early entry, the generic company has to accept additional terms of the agreement that are highly restrictive and provide the brand company with a significant amount of control over the first generic entrant. The fundamental antitrust concern on which this novel theory of harm is based is the brand company's ability to create a "pet competitor" that allows the brand company to distort the competitive process and to retain generic prices above the competitive level.

#### **4. Significance of the thesis**

Cautious analysis is important with regards to potential antitrust infringements in the pharmaceutical sector, in particular because of the highly regulated nature of the sector and the fact that analysis operates at the intersection of competition law and the law relating to intellectual property rights.

A sound antitrust policy is therefore essential, especially in the pharmaceutical sector. It is of utmost importance to strike the right balance between the incentives that spur innovation for the brand companies and the competitive price for drugs, which enhances consumer welfare. Over-enforcement could stifle innovation, whereas under-enforcement could lead to direct consumer harm.

With regards to European pay for delay settlements, the novel effects-based test proposed in this thesis does not only ensure that it is not over-inclusive in terms of general patent settlements and settlements that do not have anticompetitive effects, but it also enhances legal certainty within the

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<sup>39</sup> The European Commission has identified 87 early entry agreements in its pharmaceutical sector inquiry. These agreements included exclusivity terms such as exclusive sourcing obligations, single branding agreements, no-compete and no-challenge clauses. European Commission, *Pharmaceutical Sector Inquiry: Final Report* (2009) <<http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/index.html>>para 808.

pharmaceutical sector. The test circumvents the need for an inquiry into the validity of the patent, which is a highly fact-specific and complex task with an outcome that is difficult to predict. Instead, the test rests upon an objective cost-based analysis – an analysis that is not only more feasible for competition authorities to administer, but also for the brand and generic companies to predict.

In the case of early entry agreements, it is even more important to strike the right balance and to avoid being over-inclusive. After all, early generic entry undoubtedly has procompetitive effects as the entry leads to generic choice and lower prices prior to patent expiry. However, at the same time, early generic entry should also cause suspicion. Brand companies as profit-maximising corporations are unlikely to allow a generic company to enter prior to the expiry of their patents, without it being beneficial for the brand company in the long-run. If this were not the case, the brand company would defend its intellectual property rights aggressively against potential entry.

## **5. Methodology**

This thesis reflects the law as it stood on 30 January 2014. All online resources in this thesis were visited and verified on 30 January 2014. The last visit to these websites is therefore not mentioned hereinafter.

This thesis employs, in all four of its substantive chapters, a combination of doctrinal and comparative legal research, which comprises of the analysis of the relevant case law, decisional practice, legislation, policy documents and literature in Europe and the United States of America. These are predominantly based on the micro-comparison of the pharmaceutical regulations and fundamental antitrust principles in the United States and Europe, with the aim of illustrating differences as well as commonalities between the two regimes. These findings will determine whether categories of conduct, relating specifically to pharmaceutical antitrust present in both jurisdictions, should be dealt with differently or whether one can indeed draw from the experience and expertise in the United States. However, such a micro-comparison is only fruitful if the economic context is also taken into consideration. This becomes especially important when the already complex

intersection between competition law and intellectual property rights is analysed in relation to the highly regulated pharmaceutical sector. Without a sound understanding of the underlying legal and economic reasons behind competition policy decisions in the field of pharmaceutical antitrust, a reasoned and comprehensive comparison would not be possible. The study therefore also takes industrial economic principles into consideration, supported by empirical evidence where available.

## 6. Outline of the thesis

The thesis consists of four substantive chapters that are presented in the provided order to paint a picture of European pharmaceutical antitrust, spanning from the advent of pharmaceutical antitrust in *AstraZeneca* and the status quo to the proposed prospective enforcement priorities and policy considerations. Yet, at the same time, the chapters are self-contained and it is therefore possible for the reader to understand the contribution of the relevant chapter without having to read the rest of the thesis.

Chapter II, as the first substantive chapter of this thesis, discusses the General Court's judgment in *AstraZeneca*, the only European case of pharmaceutical antitrust that has been fully litigated to date. The discussion will focus on two aspects of judgment – namely the market definition and *AstraZeneca*'s comparative claim that the European approach, to conduct that entails the submission of misleading information to a patent office in an attempt to obtain a patent that the party is not entitled to, is overly restrictive in comparison to the relevant doctrine in the United States. The examination of both aspects aims to derive general principles not only for the benefit of future pharmaceutical antitrust investigations, but also to inform subsequent analyses in this thesis.

First, the market definition in *AstraZeneca* and the European Commission's finding of a dominant position is at issue. As the first and still the only published European antitrust decision in the pharmaceutical sector to date, the market definition in *AstraZeneca* should be seen as a major source of guidance. The European Commission has defined the relevant market in this case rather narrowly,



at least partially by the finding that doctors' inertia with regard to their prescribing and switching behaviour of the drugs in question should be regarded as an exogenous factor in market definition. This assumption is critiqued in this chapter and it is argued that doctors' inertia can in fact be decisive to the definition of the relevant market and should therefore not be categorically excluded. This critique is supported by applying the *AstraZeneca* market definition to a hypothetical pharmaceutical market of antiepileptic drugs. Empirical evidence regarding the actual substitutability of antiepileptic drugs shows that the prescribing behaviour can have a significant impact on the drug choice and, in turn, the interchangeability of drugs. This analysis suggests that the General Court's finding to exogenise doctors' prescribing inertia should not be generalised for future references. This result is not only important for Art. 102 TFEU investigations, but also in relation to the examination of market share thresholds for the application of block exemptions under Art. 101 TFEU, as it shall be explored in chapter IV.

Secondly, the chapter addresses the argument put forward by AstraZeneca during the proceedings that the conduct which the General Court's judgment found to be an infringement of Art 102 TFEU would have been barred from antitrust scrutiny in the United States by means of a detailed comparative legal analysis. This analysis comes to the conclusion that the General Court's judgment is not comparable to the so-called Walker Process Doctrine, due to major differences in the underlying antitrust principles in the US and the European Union. When compared to the more appropriate benchmark of the antitrust enforcement policy of the US Federal Trade Commission, it is shown that the FTC could indeed launch an investigation for the breach of US antitrust laws following AstraZeneca's submission of misleading information to several patent offices. Thus, contrary to the company's argument, AstraZeneca's conduct would not be immune from antitrust scrutiny in the US. In contrast to the findings in relation to market definition above, the significance of the analysis of the comparative claim does not stem from the actual results, which are nonetheless interesting, but rather from the comparative analysis itself. It highlights the important fact that, although conduct of a very similar nature might exist on both sides of the Atlantic, the respective

appropriate approach to this conduct might – and in fact should – be very different. This finding should therefore be regarded as a cornerstone for the following analyses of pay for delay settlements and early entry agreements in the European context.

Chapter III addresses each of these two types of agreements, which are entered into between brand and generic companies. The European Commission has in fact identified a number of pay for delay settlements and early entry agreements in its pharmaceutical sector. The chapter begins by describing in detail the anticompetitive potential developed by pay for delay settlements in the United States, based on the peculiarities of the Hatch Waxman Act. The chapter then turns to pay for delay settlements under the European regulatory framework and analyses the anticompetitive potential arising from them. It is argued that pay for delay settlements in Europe are not likely to exert their anticompetitive potential in the same way as in the United States, as it is not possible in Europe to automatically foreclose the relevant market by paying off a single generic entrant. That said, it could be possible for a brand company to foreclose the market depending on the actual structure of the market and the number of potential generic competitors that are present. Despite this arguably reduced anticompetitive potential, pay for delay settlements have received significant attention from the European Commission.

Early entry agreements, on the other hand, do not seem to have attracted much attention, despite being identified in the pharmaceutical sector inquiry. Although it is not disputed that generic entry prior to patent expiry can have procompetitive effects, it is argued that the European Commission should not refrain from scrutinising early entry agreements simply because of the parties' assertion of pro-competitive effects. A brand company is unlikely to allow the generic company to enter the market prior to patent expiry without gaining substantial benefits in return – these are, after all, markets that are worth billions and where the majority of the profits are realised towards the end of the patent life. The chapter therefore provides a detailed analysis of the parties' incentives to enter into an early entry agreement. Finally, for the first time, a theory of harm for early

entry agreements is developed, showing the clear potential for exclusionary conduct with the ability to distort the competitive process on the market, resulting from what the chapter describes as “the creation of a pet competitor”. The following two chapters then put pay for delay settlements and early entry agreements under detailed European antitrust scrutiny.

Chapter IV analyses pay for delay settlements under Art. 101 TFEU and Art. 102 TFEU. As part of the Art. 101 analysis, it is determined whether one could rely on previous European case law on trademark delimitation agreements and no-challenge clauses in an attempt to establish whether pay for delay settlements constitute anticompetitive agreements. Following the dismissal of this possibility, a novel “structured effects-based” approach to European pay for delay settlements is devised which takes into consideration the regulatory differences of the European pharmaceutical sector and, also, ensures against over-inclusiveness in relation to ‘normal’ patent settlements. The development of this test is inspired by the underlying rationales of the US Supreme Court’s majority opinion in *FTC v Actavis*. The Art. 102 TFEU analysis of European pay for delay settlements focuses on a potentially broader unilateral strategy by the brand company, which is facilitated by means of a pay for delay settlement. The Art. 102 TFEU investigation is therefore not complementary to the scrutiny under Art. 101 TFEU but, rather, allows for an analysis of an alternative type of conduct that nonetheless utilises pay for delay settlements.

Chapter V puts early entry agreements under antitrust scrutiny. The analysis under Art. 101 discusses the applicability of the Vertical Block Exemption Regulation and the Technology Transfer Block Exemption Regulation in the context of early entry agreements. This analysis offers a number of important insights: (1) a robust market definition is required in order to determine the applicability of block exemptions in the pharmaceutical sector; (2) early entry agreements have a number of pro-competitive effects that need to be recognised and considered when scrutinising such agreements; and (3) the anticompetitive potential of early entry agreements is raised with an increase in market power, which finally leads to an analysis of these agreements under Art. 102 TFEU. For this examination, the

brand company is presumed to be in a dominant position. The focus in this last part of chapter V is on exclusive sourcing agreements and single branding agreements as part of early entry agreements, as it is only possible for the brand company to retain control over the generic price post patent expiry if subsequent entry is deterred or at least delayed. Without the deterrence or delay of entry, subsequent generic entrants would exert competitive pressure on the early generic entrant which would lead to a reduction in the price for generic drugs in the market.

Finally, chapter VI summarises the findings of the preceding chapters and concludes the thesis, generally recommending an effects-based approach for all discussed types of conduct in pharmaceutical antitrust.

## 7. Limitations

This thesis does not consider pharmaceutical pricing and reimbursement regulations. As mentioned above, the pharmaceutical sector is highly regulated. In contrast to the actual drug approval, whose regulation is on a European level or on a national level with harmonised legislation based on secondary European legislation, pricing and reimbursement regulations are national competences which are dealt with by the relevant Member State itself. Although the pricing regulations are partially harmonised by Directive 89/105/EEC,<sup>40</sup> pricing and reimbursement differ from Member State to Member State – not only are the levels different but, even more significantly, the approaches to regulation. This means that, with the accession of Croatia to the European Union, we now potentially have – to a certain extent – 28 different regulatory systems in place across the Union. In addition, these regulations are also subject to rather frequent changes. As this thesis examines European pharmaceutical antitrust and its approach to pay for delay settlements and early entry agreements on a “macro-level”, it has been necessary to exclude the different pricing and reimbursement regulations as well as different

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<sup>40</sup> Council Directive 89/105/EEC relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion in the scope of national health insurance systems [1989] OJ L 40. The “Transparency Directive” requires the Member States to implement objective and verifiable criteria by which the decision on pricing and reimbursement are made within clear timelines and the possibility of appeal.

generic substitution regulations on the demand side from the analyses in this thesis. It is this “macro-approach” that enables the author to develop strong general arguments on a European level. Once the relevant theories of harm, the general principles and the potential approach to the investigated conduct by EU competition law is established, one can apply these findings on a case-by-case basis to different Member States. This is however outside the scope of this thesis.

Nonetheless, the conclusion alludes to the potential exacerbating and mitigating effects that the different pricing and reimbursement regulations might have on the established principles – setting the scene for potential future research.

## II. ASTRAZENECA - THE ADVENT OF EUROPEAN PHARMACEUTICAL ANTITRUST<sup>1</sup>

### 1. Introduction

This chapter should be seen as a prologue to the analyses in the following chapters of this thesis. The General Court's judgment in *AstraZeneca*, which was upheld by the ECJ, is the first judgment addressing issues of pharmaceutical antitrust on a European level.<sup>2</sup> The General Court ruled for the first time on the European Commission's *ex post* definition of the relevant market in a pharmaceutical antitrust case and addressed the issue of misuse of procedural rules and the potential anti-competitive harm of such misuse in the context of intellectual property rights in the highly regulated pharmaceutical sector. In its judgment the General Court upheld the European Commission's finding that AstraZeneca had abused its dominant position by acquiring patent extensions, which it would not have been entitled to.

As it is the only fully litigated case in European pharmaceutical antitrust to date, one would hope to be able to refer to this judgment as guidance in current and future antitrust investigations in the pharmaceutical sector. Particularly in relation to market definition in the pharmaceutical sector it would be highly beneficial to receive guidance from the EU courts in order to create legal certainty for the business sector. The sector is heavily relying on intellectual property rights and is also highly regulated. Both of these facts are likely to have a significant impact on market power of pharmaceutical companies.

The first main objective of this chapter is therefore to establish whether general principles can be derived from the market definition as decided by the European Commission and upheld by the EU courts in the *AstraZeneca* judgment. It will be shown in a detailed analysis, unfortunately, that the market definition in

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<sup>1</sup> Parts of this chapter have been published in the European Competition Journal. See S Gallasch, *AstraZeneca vs. the Walker Process – A real EU-US divergence or an attempt to compare apples to oranges* (2011) 7 (3) European Competition Journal 505.

<sup>2</sup> Case T-321/05 *AstraZeneca v European Commission* [2010] ECR 00; upheld by Case C-457/10 P *AstraZeneca v European Commission* (ECJ, 6 December 2012).

*AstraZeneca* offers only limited guidance to the pharmaceutical business sector and that it is difficult for pharmaceutical companies to derive general principles that would aid them in the assessment of their position in the relevant market. In terms of this thesis market definition becomes relevant in the discussion whether the brand company abuses its dominant position with regard to pay for delay settlements<sup>3</sup> and early entry agreement. Furthermore, market definition becomes important in the assessment of the market share thresholds of block exemptions in relation to early entry agreements.<sup>4</sup>

However, establishing whether the judgment can be used as guidance in relation to market definition is not the sole reason for the analysis of this judgment. The analysis of the process leading up to the EU Court's judgment, including AstraZeneca's appeal<sup>5</sup> of the European Commission's decision<sup>6</sup> and the General Court's judgment allows for a discussion of the importance of careful comparative legal analysis in cases where significant expertise and experience exist in one jurisdiction. The question that arises is whether one should rely on this experience in a jurisdiction which lacks such experience due to the novelty of the investigated conduct. In the case of *AstraZeneca*, the defendants argued throughout the entire investigation and in front of the EU courts that the novel finding of abuse committed through the submission of misleading information was overly restrictive.<sup>7</sup> AstraZeneca supported this claim by referring to a US judicial doctrine, called the Walker Process Doctrine, and the relevant case law in the United States, which addresses a similar conduct to that which was under investigation in Europe. Nonetheless, the European Commission and the General Court unanimously rejected this comparative argument and instead developed a European approach to

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<sup>3</sup> The predominant focus with regard to pay for delay settlements is on the anticompetitive agreement between the brand company and the generic entrant, but as it is discussed below, the brand company could also use a pay for delay settlement in order to facilitate a broader unilateral strategy. See Chapter III sec.3.

<sup>4</sup> Chapter IV sec. 2.

<sup>5</sup> *AstraZeneca/ Commission (Case T-321/05)* Appeal to the General Court (25 August 2005) OJ C 271/24.

<sup>6</sup> *AstraZeneca* (Case COMP/A. 37.507/F3) Commission Decision 2006/857/EC, [2005] OJ L 332.

<sup>7</sup> See *AstraZeneca v European Commission* (n 2) para. 316, 317 (all numbers in relation to the AstraZeneca judgment refer to paragraphs); *AstraZeneca/ Commission* (n 5).

the conduct in question.<sup>8</sup> A detailed comparative legal analysis of the European approach and the Walker Process Doctrine shows that the European Commission and the EU courts were correct to reject the comparative argument based on the US Walker Process Doctrine, as the EU and US antitrust regimes and their respective underlying principles are too different to allow one to seek guidance from the US jurisprudence, despite the fact that the investigated conduct is very similar.

This finding has important ramifications for the analyses in the subsequent chapters of this thesis, which discuss pay for delay settlements and early entry agreements in the pharmaceutical sector. Pay for delay settlements in particular have attracted significant antitrust scrutiny in the United States, which has led to a substantial body of case law and significant expertise for the US antitrust authorities. Just as in the case of *AstraZeneca*, the key question that arises in these analyses is whether the European Commission should rely on the US expertise or whether it should rather develop its own European approach to pay for delay settlements and early entry agreements.

Considering the thesis as a whole, the discussion of the *AstraZeneca* judgment in this chapter should be seen as already mentioned above as a prologue to the remaining chapters that highlights two points. On the one hand, it highlights the difficulties that might arise in future pharmaceutical antitrust investigations in relation to market definition. On the other hand, it emphasises the possible need to develop a European approach to pay for delay settlements and early entry agreements and advocates for careful consideration before drawing from the extensive US expertise in relation to issues of pharmaceutical antitrust.

The chapter is structured as follows. First it provides a brief overview of AstraZeneca's conduct that led to the antitrust investigation (Section 2), the European Commission's decision (Section 3) and AstraZeneca's appeal of this decision to the General Court (Section 4). AstraZeneca's pleas in relation to the definition of the relevant market and the comparative argument in relation to the

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<sup>8</sup> See *AstraZeneca v European Commission* (n 2) 340-343 (the European Commission's rejection) and 368 (the General Court's rejection of the argument).



US jurisprudence are then discussed in detail (Sections 5 and 6). The analysis begins by addressing the General Court’s findings in relation to both issues, but then goes beyond the discussion of the actual findings of the Court.

In relation to the Court’s market definition, it is argued, in Section 5, that the definition in *AstraZeneca* is too fact-specific to derive general principles that can be used for guidance. This argument is supported by the application of the market definition in *AstraZeneca* to scenarios taking place in a hypothetical market for antiepileptic drugs. The impact of the key factor in the *AstraZeneca* market definition – namely, the disregard of doctors’ prescribing behaviour – will be at the centre of this discussion.

With regard to AstraZeneca’s comparative argument, Section 6 starts by providing a detailed discussion of the Walker Process Doctrine and the relevant case law. Following this discussion it is argued that the General Court’s findings and the Walker Process Doctrine should not be compared, as the respective underlying antitrust principles are too different. In a further step, the comparative analysis shows that the findings of the General Court are not overly restrictive in comparison to the US approach when compared to the more appropriate enforcement regime of the Federal Trade Commission under section 5 of the FTC Act. This analysis is followed by the conclusion (Section 7).

## **2. AstraZeneca’s conduct**

AstraZeneca is one of the world’s largest innovative pharmaceutical companies and has its headquarters in London. The company is involved in the entire process of pharmaceutical production and marketing. It is discovering new pharmaceutical compounds, is developing the drug, manufacturing it and finally marketing the finished product. Its innovative focus lies in different areas of healthcare, including cancer, cardiovascular, gastrointestinal, infection, neuroscience, and respiratory and inflammation.<sup>9</sup>

One of AstraZeneca’s most successful innovations is a drug called Losec. Based on the active ingredient omeprazole, the drug provides treatment for

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<sup>9</sup> AstraZeneca website <<http://www.astrazeneca.com/about-us/key-facts/>>.

gastrointestinal diseases whose effects are more commonly known as reflux and heartburn. Losec gained its market authorisation in the late 1980s and was subsequently launched in Europe.<sup>10</sup> In 1996, Losec became the world's best-selling prescription drug.

AstraZeneca filed a patent application with the European Patent Office on the 3 April 1979, which would provide patent protection in nine European Member States – namely Belgium, Luxembourg, the Netherlands, Switzerland, Germany, France, the United Kingdom, Italy and Sweden.<sup>11</sup> Additionally, AstraZeneca filed patent applications in several other European Member States that, at the time, had not yet joined the European Patent Convention, such as Denmark, Finland, Austria and the Republic of Ireland.<sup>12</sup> The patent applications lodged with the European Patent Office as well as the other national patent authorities were finally granted and thereby provided AstraZeneca with patent protection for omeprazole and thus Losec. The patent protection term lasted for 20 years from the filing date of the patent application,<sup>13</sup> meaning it expired between April and August 1999, depending on the actual filing date in the respective above mentioned countries.

Wary that its sales of Losec would severely decline after the term of patent protection had ended, AstraZeneca tried to extend its patent protection by applying for supplementary protection certificates (SPCs) in all Member States that granted an original patent for Losec.

In the effort to mitigate for the reduction of effective term of patent protection caused by the delay between the filing of a patent application and the grant of the final market authorisation for a drug, the SPC grants the applicant a patent extension of a maximum of five years from the date on which the protection for the initial patent elapses.<sup>14</sup>

In 1993 and 1994, AstraZeneca filed SPC applications with several national patent authorities to obtain a patent extension. During this application process,

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<sup>10</sup> *AstraZeneca* (n 6) para. 17 (all numbers in relation to the AstraZeneca decision refer to paragraphs)

<sup>11</sup> These nine Member State were the first Member State to join the European Patent Convention which is the legal bases for issuing of a European patent.

<sup>12</sup> *AstraZeneca* (n 6) 21.

<sup>13</sup> Art. 63 (1) of the European Patent Convention.

<sup>14</sup> Art. 13 (1) of the European Patent Convention.

AstraZeneca provided the patent offices with misleading information regarding the date of the first market authorisation for Losec in the European Union. This date is an essential requirement for the application as it determines the exact date on which the protection period of the SPC commences and logically the last day of protection.

On 12 May 1999, two generic competitors, Generics (UK) Limited and Scandinavian Pharmaceuticals Generics, filed a joint complaint with the European Commission about AstraZeneca's conduct, which led to proceedings against AstraZeneca by the European Commission that were initiated on 25 July 2003.

### **3. European Commission's *AstraZeneca* decision**

In 2005, the European Commission found in its decision that AstraZeneca had abused its dominant position in the market for proton pump inhibitors (PPI) in two different ways. The first abuse was found to be AstraZeneca's acquisition of supplementary protection certificates (SPC) for patents following the misleading representation before several patent offices. The second abuse was the selective deregistration of the capsule-version of Losec and replacing it with a tablet-version Losec MUPS. Following these two infringements of Art. 102 of the Treaty on the Functioning of the European Union (TFEU), the European Commission fined AstraZeneca for EUR 60 million. AstraZeneca appealed this decision to the General Court. Before this section addresses the grounds for AstraZeneca's appeal, the European Commission's definition of the relevant market and the findings regarding the two types of abuse are briefly discussed in turns.

#### **3.1. European Commission's market definition**

In the case of *AstraZeneca*, the market for gastrointestinal acid-related diseases was of concern – more precisely the market surrounding AstraZeneca's blockbuster anti-ulcer drug Losec. AstraZeneca's Losec was based on the active ingredient omeprazole, which works as a proton pump inhibitor (PPI). “[It] proactively inhibits

*acid secretion into the stomach [and] was the first on the market to act directly on the proton pump, that is to say, the specific enzyme inside the parietal cells along the stomach wall, which pumps acid into the stomach.*"<sup>15</sup> Prior to the market entry of Losec, patients suffering from an ulcer were treated with antihistamines, so-called H2 blockers. The question which had to be answered by the European Commission was whether PPI drugs based on omeprazole and H2 blockers belonged to the same market or were to be regarded as separate product markets.

The European Commission started the definition of the relevant product market on the ATC 3 level of "drugs for the treatment of peptic ulcer".<sup>16</sup> This ATC class, "A2B", includes five different types of drugs: (1) H2 blocker, (2) PPI, (3) prostaglandis, (4) bismuth antiulcerants, and (5) other antiulcerants. However, the European Commission narrowed down its analysis to the first two groups of drugs, as they are the only types of drugs which directly inhibit the source of the acid production, whereas the other three categories only remedy the effects caused by the acid.<sup>17</sup>

To finally decide whether H2 blocker and PPI are in the same or separate product markets, the European Commission focussed on a number of factors including: (1) mode of action, (2) therapeutic use, (3) demand and price and (4) natural events. These factors will be discussed in turn.

The mode of action describes the way in which the drug in question produces its therapeutic effects. This factor has been previously used by the European Commission in merger analyses to differentiate between drugs and to

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<sup>15</sup> Case C-457/10 P *AstraZeneca v European Commission* (ECJ, 6 December 2012), Opinion of AG Mazák, para. 3.

<sup>16</sup> *AstraZeneca* (n 6) 372. The Anatomical Therapeutic Chemical (ATC) classification system divides products into different groups according to their anatomical site of action, therapeutic indications, composition, mode of action etc. ATC1 describes the anatomical site of action, i.e. cardiovascular system; ATC2 describes the therapeutic main groups within ATC1, including information about the indication, the therapeutic sub groups and the anatomical system; ATC3 includes pharmacological information about the drug in question, such as the intended use; ATC4 contains detailed pharmacological information on molecule level such as the actual formulation, the chemical description and mode of action. On ATC4 level the group may consist of a single molecule. WHO, 'ATC – Structure and principles' < [http://www.whocc.no/atc/structure\\_and\\_principles/](http://www.whocc.no/atc/structure_and_principles/)>.

<sup>17</sup> *Ibid.* 375.

define the relevant market.<sup>18</sup> In the *AstraZeneca* decision the respective mode of action of PPI and H2 blocker proved to be a distinctive factor. Both drugs proactively inhibit the acid secretion in the stomach, but PPI is the only drug that is directly blocking the proton pump. The proton pump is an enzyme which is situated in the so-called parietal cells in the stomach walls and is injecting acid into the stomach – causing ulcers and other acid related conditions. In contrast to this direct effect, H2 blockers only have an indirect effect on acid secretion in the stomach. They block histamine receptors in the same parietal cells which act as a stimulant for the proton pump. Apart from histamine receptors, other stimulants include the hormone gastrin but also caffeine and other foodstuffs.<sup>19</sup> H2 blockers can therefore be seen as a partial solution to the problem by blocking one of many stimulants for acid production, whereas PPI goes to the root of the problem and blocks the acid producing enzyme itself.

Despite the fact that it was seen as insufficient to define the market based on this distinction alone, the differences in the mode of action are closely linked to the therapeutic use of the drugs and have a significant impact on the functional substitutability between PPI and H2 blockers.<sup>20</sup> Functional substitutability should not be solely determined by whether the drugs considered are prescribed for the same illnesses, but should also take into consideration their efficiency and appropriateness as a remedy against a certain illness.<sup>21</sup> Based on medical evidence, statistical information provided by IMS Health<sup>22</sup> and internal documentation by AstraZeneca, the European Commission has shown that AstraZeneca's Losec has been the more cost-effective and therapeutically superior drug to H2 blockers in all cases considered.<sup>23</sup> Omeprazole has been superior to H2 blockers in terms of healing rates, symptoms relief and eradication rates. Losec was regarded as "first line" treatment and the only adequate treatment in severe cases of peptic ulcer

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<sup>18</sup> E.g. *Sanofi-Synthelabo/Aventis* (COMP/M. 3354) Commission Decision 2004/C 213/03 [2004] OJ C213 para. 30.

<sup>19</sup> *AstraZeneca* (n 6) 34.

<sup>20</sup> *Ibid.* 377, 380.

<sup>21</sup> *Ibid.* 381.

<sup>22</sup> IMS Health is one of the leading companies providing detailed analytical data on the pharmaceutical sector.

<sup>23</sup> *AstraZeneca* (n 6) 386, 393.

diseases, as it could heal patients who were resistant to being treated with H2 blockers.<sup>24</sup>

The therapeutic superiority of Losec was also underlined by the higher price that AstraZeneca was able to extract. The higher price was used as an indicator for superiority based on the consideration that high prices can only be extracted from public authorities, if they regard the therapeutic value and the therapeutic innovation of the new drug as superior.<sup>25</sup>

Finally, the European Commission relied on “natural events” in support of its definition of the relevant market, excluding H2 blockers. Generic entry of H2 blockers and PPI was used to establish potential shocks to price and sales of brand H2 blockers and PPI. The European Commission observed that the entry of generic H2 blockers in Germany had an adverse effect on the prices of brand H2 blockers, whereas the price of Losec and the sales of other PPIs remained unaffected.<sup>26</sup> In contrast to the entry of generic H2 blockers, the launch of generic omeprazole in Germany had a significant impact on sales volume as well as the market share of Losec.<sup>27</sup> Following this evidence, the European Commission concluded that H2 blockers do not exert significant competitive pressure on Losec and thus they should not be seen as part of the same market.

### **3.2. European Commission’s finding of abuse**

In its decision against AstraZeneca, the European Commission found two different types of abuse in the investigated conduct.

‘The [first] abuse consists of AstraZeneca’s pattern of misleading representations as part of its SPC Strategy for omeprazole during two stages with a view to preventing, or at least delaying, generic market entry.’<sup>28</sup>

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<sup>24</sup> Ibid. 39, 40, 44.

<sup>25</sup> Ibid. 385.

<sup>26</sup> Ibid. 423.

<sup>27</sup> Ibid. 425.

<sup>28</sup> Ibid. 773.

The first stage constituted the initial submission of misleading information to the relevant patent offices in relation to the date of the first marketing authorisation that AstraZeneca had received for its drug Losec, concealing two earlier dates.<sup>29</sup> In the second stage, AstraZeneca provided further misleading information to the patent offices which raised further questions regarding the company's SPC applications. The same kind of misleading representations were also made in the context of court proceedings brought by generic companies who sought to invalidate AstraZeneca's SPCs.<sup>30</sup>

The second abuse identified by the European Commission found was AstraZeneca's selective deregistration of marketing authorisations for the capsule version of Losec in combination with the switch from the capsule version to a tablet-based version called Losec MUPS.<sup>31</sup> According to the European Commission, it had been AstraZeneca's intention to delay generic entry through technical and legal hurdles.<sup>32</sup> AstraZeneca's choice of countries to employ this strategy was dictated by the chances of achieving its exclusionary aim of bridging the gap between the expiry of the patent and SPC protection and the launch of the new version of the drug.<sup>33</sup>

#### **4. AstraZeneca's appeal to the General Court<sup>34</sup>**

On 25 August 2005, AstraZeneca appealed to the General Court seeking to quash the European Commission's decision.<sup>35</sup> The appeal challenged the European Commission's definition of the relevant market and the finding of abuse.

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<sup>29</sup> Ibid. 628.

<sup>30</sup> Ibid. 629.

<sup>31</sup> The second abuse is addressed for the sake of completeness. It is not separately discussed in this chapter, as it is unlikely that this abuse arises again. Council Directive 2001/83/EEC as the relevant secondary legislation that made this abuse possible has been replaced Directive 2004/27/EEC, which no longer provides the possibility to delay generic entry by withdrawing marketing authorisations.

<sup>32</sup> *AstraZeneca* (n 6) 788.

<sup>33</sup> Ibid. 789.

<sup>34</sup> AstraZeneca has appealed the judgment of the General Court to the ECJ on 6 November 2010 but the ECJ upheld the General Court's judgment and dismissed AstraZeneca's appeal in its entirety *AstraZeneca v European Commission* (n 2) 168. Therefore the focus in this chapter is on the General Court's judgment.

<sup>35</sup> *AstraZeneca/ Commission* (n 5).

With regards to market definition, AstraZeneca argued that the European Commission had made an error of assessment by defining the relevant market as being only that of proton pump inhibitors (PPI), used for the treatment of gastrointestinal acid-related diseases, and by excluding histamine receptor antagonists (H2 blockers) from the relevant market.<sup>36</sup> This appeal was based, among other pleas in law, on the “*alleged manifest error of assessment as to the relevance of the gradual nature of the increase in use of PPIs at the expense of H2 blockers.*”<sup>37</sup> AstraZeneca claimed that the prescription rate for Losec only increased gradually over time and that it had never replaced H2 blockers completely. In fact, in most of the countries concerned, H2 blockers retained a significant percentage of prescriptions, approximately 20 per cent.<sup>38</sup> According to AstraZeneca, this delayed and gradual increase of the prescription rate regarding Losec was caused by the prescribing doctors, who are largely focused on therapeutic effectiveness and appropriateness, and their inertia to switch from H2 blockers to Losec due to an increased risk of side-effects.<sup>39</sup> It was thus argued by AstraZeneca that H2 blockers should have been included within the same market as PPI, as H2 blockers exert significant competitive pressure on PPI; a proposition that is supported by the fact that the sales of Losec increased in a gradual manner at the expense of H2 blocker sales.<sup>40</sup>

Challenging the European Commission’s finding of abuse, AstraZeneca argued that submitting misleading representation to the patent office could not amount to an abuse unless the relevant patent was dishonestly obtained and was in fact enforced or at least capable of being enforced.<sup>41</sup> In making this claim, AstraZeneca had essentially asked the General Court to consider the US Walker Process Doctrine.<sup>42</sup> The doctrine itself is not referred to *expressis verbis* in the

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<sup>36</sup> *Ibid.*

<sup>37</sup> *AstraZeneca v European Commission* (n 2) 29.

<sup>38</sup> *Ibid.* 37.

<sup>39</sup> *AstraZeneca v European Commission* (n 2) 34, 38.

<sup>40</sup> *Ibid.* 36.

<sup>41</sup> *AstraZeneca/ Commission* (n 5).

<sup>42</sup> *Walker Process Equipment, Inc. v. Food Mach. & Chem. Corp.* 382 U.S. 172 (1965) dealing with fraudulent patent procurement by means of misrepresentation in front of the United States Patent and Trademark Office (USPTO). The doctrine provides the defendant in a patent infringement



appeal, but the appeal does allude to the requirements that need to be fulfilled in order to invoke the Walker Process Doctrine successfully. Furthermore, Frances Murphy, who acted as AstraZeneca's general counsel in this case, has published a case comment advocating for the consideration of the Walker Process Doctrine and its requirements by the EU courts.<sup>43</sup> AstraZeneca also challenged the second abuse concerning the selective deregistration of marketing authorisations in relation to Losec as an improper interpretation of Art. 102 TFEU, claiming that there should be no obligation to maintain a marketing authorisation for a product that is no longer marketed.<sup>44</sup>

Following this brief account of AstraZeneca's appeal to the General Court, the remainder of this chapter addresses the Court's findings in relation to market definition and the first abuse.<sup>45</sup> The discussion of both of these issues extends beyond the findings of the Court.

In relation to the Court's definition of the relevant market the more general question is addressed; namely, whether the market definition of the *AstraZeneca* judgment can be used as guidance for future pharmaceutical antitrust investigation following Art. 102 TFEU. Such guidance would be desirable for the pharmaceutical business sector especially in relation to market definition, as *AstraZeneca* is the first, and so far, only market definition in the field of pharmaceutical antitrust. After the application of the market definition to the hypothetical market for antiepileptic drugs (which shows that only limited general guidance can be derived from the *AstraZeneca* judgment in relation to market definition), the discussion turns to the Court's findings of abuse. A detailed analysis of AstraZeneca's plea to consider a US legal doctrine and the relevant US case law is then undertaken. A comparative analysis of the US Walker Process Doctrine and the General Court's findings of

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lawsuit with possibility to bring an antitrust counterclaim against the plaintiff on the basis that the litigated patent has been obtained by fraud. This is an exception to the antitrust immunity in US private patent litigation. The doctrine is discussed in detail *infra* sec. 6.1.1.

<sup>43</sup> Frances Murphy, 'Abuse of regulatory procedures - the AstraZeneca case: Part 2, Case Comment' (2009) 30 (6) *European Competition Law Review* 289.

<sup>44</sup> *AstraZeneca/ Commission* (n 5).

<sup>45</sup> As mentioned above, the second abuse is not discussed in this chapter. Its brief discussion in section 3.2. is for the sake of completeness.

abuse will proceed to showcase and highlight the importance of careful consideration before drawing from the experience and expertise of the US Federal Trade Commission and the US jurisprudence. Such a careful approach to comparative analyses is especially warranted if the investigated type of conduct originates in one jurisdiction and now also surfaces in another jurisdiction, as is the case for pay for delay settlements. In terms of this thesis, the outcome of the comparative analysis in this chapter should act as a constant reminder that similar conduct should not necessarily be treated in a similar way.

## **5. The General Court’s findings on market definition**

In its judgment, the General Court rejected AstraZeneca’s pleas of law. Its examination particularly focussed on whether doctors’ inertia would lead to a competitive constraint by H2 blockers. The European Commission found that doctors’ inertia is an exogenous factor to market definition which is inherent in the pharmaceutical prescription market and, as such, should be disregarded.<sup>46</sup> It does not impose a competitive constraint akin to brand loyalty generated by past reputation or advertising, it is unrelated to competition on the merits and it autonomously dampens demand for a new product.<sup>47</sup> The General Court stated that a causal link between the gradual increase of Losec sales at the expense of H2 blocker sales and therefore a competitive constraint exercised by H2 blockers over PPI cannot be sufficiently established and that a presumption of such a causal link does not exist in principle.<sup>48</sup> Although the General Court acknowledged that the degree of inertia slowed down the substitution of PPIs for H2 blockers, it nonetheless held that such inertia did not exercise a competitive constraint over PPI, as the inertia was based on the accumulation and dissemination of information amongst prescribing doctors as opposed to the quality of H2 blockers.<sup>49</sup>

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<sup>46</sup> *AstraZeneca* (n 6) 467.

<sup>47</sup> *AstraZeneca v European Commission* (n 2) 56.

<sup>48</sup> *Ibid.* 92, 93.

<sup>49</sup> *Ibid.* 47.

Leaving the criticism of the market definition in the specific case of *AstraZeneca* to one side,<sup>50</sup> the focus of this section is on the more general and I think even more important question of whether the pharmaceutical industry can derive general guidance from this market definition.

Fundamentally it has to be asked whether the European Commission and the EU courts have been correct in finding that doctors' prescribing inertia should be an exogenous factor to market definition and that such inertia should only play a role when the inertia is based on drug quality concerns, rather than concerns related to possible side-effects.<sup>51</sup>

In order to establish the general applicability of this finding, the EU courts' approach to market definition is applied to a hypothetical market based on information acquired through a case study of antiepileptic drugs. The analysis of this hypothetical scenario shows that doctors' prescribing inertia in relation to side-effects is a key factor to determine a realistic market in this case. Fundamentally, this analysis shows that it is not possible to draw general conclusions from the market definition in *AstraZeneca* that could be used as guidance for future antitrust investigations in the pharmaceutical sector.

### **5.1. The market definition's lack of general guidance**

The unfortunate lack of general guidance that can be derived from the market definition in the *AstraZeneca* judgment can be highlighted by the definition of a hypothetical market in this section. The EU courts' approach to market definition is

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<sup>50</sup> Murphy heavily criticises almost every part of the decision in a number of articles. This is however not surprising as she was acting legal counsel for AstraZeneca. Frances Murphy and Francesco Liberatore, 'Abuse of regulatory procedures - the AstraZeneca case' (2009) 30(5) European Competition Law Review 223; Murphy (n 43); David W Hull, 'The application of EU competition law in the pharmaceutical sector' (2011) 2 Journal of European Competition Law & Practice 481 argues that the dynamic approach to the estimation of competitive constraints of the European Commission is likely to create a high level of uncertainty for innovating pharmaceutical companies. While a new arguably superior drug enters the market and starts to increase its market share, it will be at least difficult to establish in the initial stages whether the legacy drug is going to exert any competitive pressure, whether this competitive pressure decreases over time due to delayed switching behaviour due to doctor's inertia, and finally the extent to which the new drug is replacing the legacy drug.

<sup>51</sup> *AstraZeneca v European Commission* (n 2) 47; Case C-457/10 P *AstraZeneca v European Commission* (n 2) 50.

applied to a hypothetical market based on information acquired through a case study of antiepileptic drugs. The analysis of this hypothetical scenario shows that doctors' prescribing inertia in relation to side-effects is a key factor to determine a realistic market in this case and should therefore be regarded as endogenous.

As mentioned above, the market scenario in *AstraZeneca* is very specific, as one brand drug effectively replaces another brand drug. In economic terms this scenario could be described as a vertically differentiated market. In a vertical differentiation model products differ in quality and this quality difference causes the consumers to prefer one product over the other.<sup>52</sup> Under this model, everyone agrees on the quality of the product and would normally buy this product. Differences occur only because of differences in income, as not everyone can afford the product.<sup>53</sup> In the case of *AstraZeneca*, the introduction of Losec constituted a new innovative step in the anti-ulcer treatment, superseding H2 blockers as the preferred treatment because of its therapeutic superiority. If the distribution of income is narrow enough, only one undertaking will operate in the market, as everyone buys the product of superior quality, which ultimately leads to a monopoly.<sup>54</sup> In this case, the switching behaviour of prescribing doctors can be regarded as exogenous.

However, it is questionable whether the approach to regard doctors' prescribing inertia as exogenous to market definition is transferrable to other scenarios in the pharmaceutical sector. This could especially be the case, in a horizontally differentiated market in which generic companies are involved in a scenario which has led to an antitrust investigation. In contrast to a vertical differentiation model, a horizontal differentiation model describes a market in which consumers differ in their preferences over varieties of the same product.<sup>55</sup> A simple example illustrating horizontal differentiation is the cement market, in which a number of companies offer cement in different geographical locations. Customers

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<sup>52</sup> Simon Bishop and Mike Walker, *The economics of EC competition law: Concepts, application and measurement* (3<sup>rd</sup> edn, Sweet & Maxwell, London 2010). 3-035

<sup>53</sup> Massimo Motta, *Competition policy: Theory and practice* (1<sup>st</sup> edn, Cambridge University Press, Cambridge, 2004) 77.

<sup>54</sup> *Ibid.*

<sup>55</sup> *Ibid.*

would choose the company to buy the cement from not on the basis of product but merely on the convenience of their location.<sup>56</sup> When translating this example into the pharmaceutical sector, one should consider a market in which several drugs can treat the same medical condition, with generic drugs being the ultimate example for a horizontally differentiated product because they have to, by law, be bioequivalent to the brand version of the drug. Vertical differentiation in terms of quality should not be an issue in this case.

This section therefore uses two scenarios to illustrate a hypothetical market definition of a horizontally differentiated market in the pharmaceutical sector – (1) a scenario in which a generic company enters the market prior to patent expiry of the brand drug with the permission of the brand company, followed by subsequent generic entry after patent expiry and (2) a scenario in which the brand company is paying off the generic company for not entering the market. The hypothetical analysis has two stages. First it defines the market based on the assumption that doctors' prescribing behaviour is exogenous. However, following this stage it is not possible to explain the significant first-mover advantage that the first generic entrant has over subsequent entrants. The second stage therefore endogenises doctors' prescribing behaviour. The analysis of a hypothetical horizontally differentiated market in which the prescribing behaviour is taken into consideration provides a market definition that is more realistic and precise. Additionally, the analysis leads to a smaller market with potentially higher market shares of the market players.

#### **5.1.1. The early generic entry scenario**

Imagine a scenario in which three different brand companies produce three different brand drugs (A, B and C). All treat the same medical condition, using slightly different modes of action but achieving equivalent efficiencies (Fig. 1). So far no generic versions of any of these brand drugs exist on the market. This changes when one generic company (GA) agrees with the first brand company

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<sup>56</sup> Bishop and Walker (n 52) 3-034.

producing A to enter the market before the patents that cover A expire at time (t), thus being the only generic drug on the market in this therapeutic area and the only generic version of drug (A). After the expiry of the patents which protect drug A, a second generic company with a generic version of brand drug (A) enters the market at time (t+1). At a later point in time (t+2) which is not related to the patent expiry of drug A but rather the expiry of the patent protection of drug B, a company with a generic version of brand drug (B) enters the market.

In the following, this scenario is developed step by step, discussing the anticipated diversion of sales from the horizontally differentiated brand drugs (A, B and C) to the generic drugs and the change of these diversions after each generic entry. It is assumed that the subsequent generic entrant GA2 and GB enter the market respectively at a price which is 10 per cent below the previous entrant. It is further assumed that decision makers in this scenario, the prescribing doctor and the dispensing pharmacists are acting as “reasonable” agents. Any type of inertia is explicitly excluded. The only regulatory constraint that is taken into consideration at this stage is the regulations regarding the mandatory or indicative generic substitution by pharmacists.

In contrast to the situation in *AstraZeneca*, the market in question is not vertically differentiated, but rather horizontally differentiated. Neither of the brand drugs can be characterised as “new” drug or as “legacy” drugs. None of the drugs have the therapeutic superiority which would enable it to replace the other drugs. Assuming similar modes of action and equivalent efficiency, all three drugs should be regarded as functionally interchangeable, thus putting them in the same relevant market.

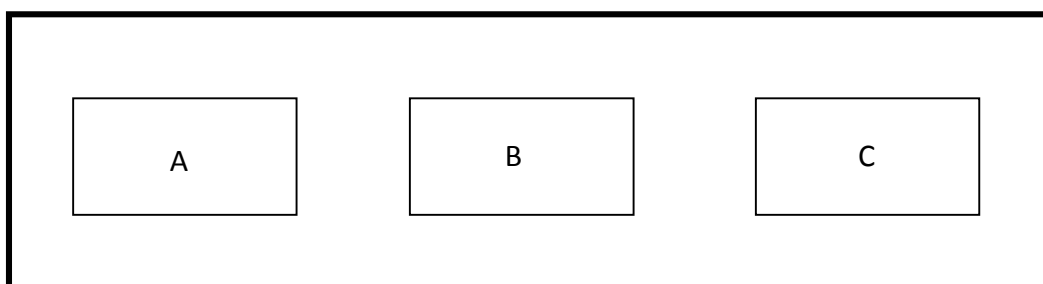


Fig. 1: Initial market of 3 horizontally differentiated drugs

The fundamental question is whether this scenario changes once generic companies enter the market. As noted above, generic versions of brand drugs are regarded as closest substitutes to the brand version because of the bioequivalence requirement. Hence, they are part of the same product market as the brand versions. It should therefore also be assumed that generic drugs exert competitive pressure not only on the brand drugs in the market but also on the other generic drugs. Due to their bioequivalence, one would also expect similar market share ratios for the generic drugs.

In this scenario, generic company GA1 is entering the market following the conclusion of a so-called early entry agreement with brand company A. Thus GA1 can enter the market prior to the expiry of the patents which protect brand drug A from generic competition at time (t). Being the first entrant and the closest substitute to brand drug A, GA1 is likely to exert significant competitive pressure by diverting a significant percentage of sales from A to GA1. The sales diversion (d) from A to GA1 is increased by the generic substitution laws that are likely to be in place. Even if the prescribing doctor is not switching his patients from A to GA1, in most European Member States the dispensing pharmacist is likely to make this switch. In certain Member States, the pharmacist is obliged to substitute a brand drug with a generic version once available (mandatory substitution), in other Member States such a substitution is the decision of the doctor and/or the pharmacist (indicative substitution) and in a few Member States such automatic substitution is not permitted at all.<sup>57</sup> Thus the level of competitive pressure should differ from Member State to Member State depending on the regulatory system in place.

The degree of diversion of sales (d) from B and C after the entry of GA1 is likely to be smaller than the diversion from A to GA1, as illustrated by the narrower arrows below (Fig. 2). These differences are caused by the generic drug substitution regulation. Pharmacists are not allowed, under any of aforementioned substitution systems, to switch patients from B and C to GA1. This decision can only be made by

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<sup>57</sup> Sabine Vogler, *PPRI report: pharmaceutical pricing and reimbursement information* (Gesundheit Österreich GmbH Geschäftsbereich ÖBIG, Vienna 2008) 106.

the prescribing doctor who has to specifically prescribe GA1. So despite brand drugs B, C and generic GA1 being therapeutically interchangeable in theory, the actual substitution depends on the doctor's prescription behaviour. However, assuming a "reasonably acting doctor", one should expect significant diversions of sales from B and C to GA1 due to the therapeutic substitutability, on the one hand, and the significant price differentials, on the other, which lead to significant cost savings.<sup>58</sup>

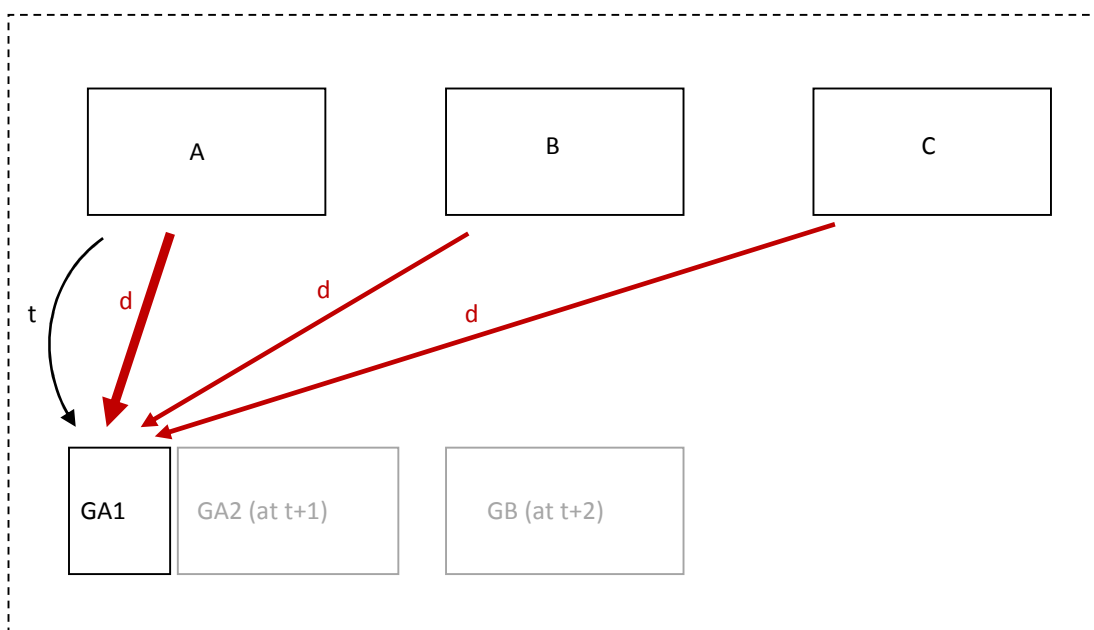


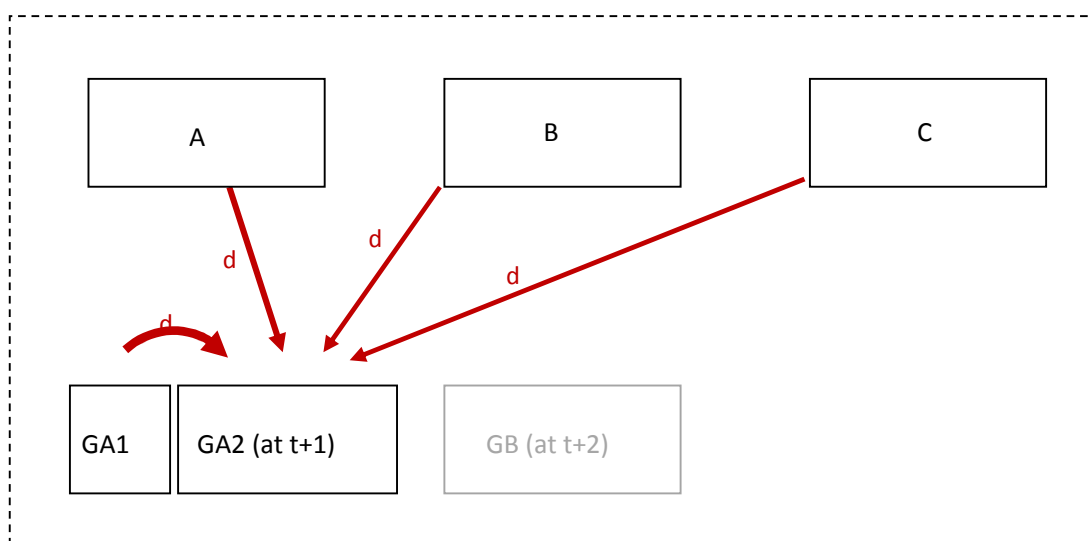
Fig. 2: Diversion of sales after "early entry" of GA1

With the entry of GA2 at the time of the expiry of the patents protecting brand drug A ( $t+1$ ), the diversion of sales ( $d$ ) would be expected to shift (Fig.3). The most significant diversions should again be experienced between A-GA2 and GA1-GA2. This effect is again owed to the generic substitution regulation in place. In these two cases, the dispensing pharmacist might be obliged or encouraged because of the generic substitution regulation to switch the patient from A to GA2 or from GA1 to GA2 due to the decreased price of GA2. The differentiated nature of the market is likely to result in a higher degree of diversion of sales from GA1 to GA2 than from A to GA2. This is due to the fact that patients who have already been switched once

<sup>58</sup> The potential competitive pressure of GA1 on B and C does not translate into reversed competitive pressure by B and C on GA1, largely because of the price differentials of brand drugs and generic drugs. However, such asymmetric competitive pressure has been acknowledged by the General Court in its AstraZeneca judgment.



from A to GA1 are less likely to have any form of brand loyalty towards the brand and thus should not be opposed to a second switch. Nonetheless, substantial sales should also be diverted from A to GA2 due to the increased price differentials. The diversion from B and C to GA2 should be similar or slightly increased compared to the previous stage regarding GA1, as the scenario has not changed much; doctors would still have to explicitly prescribe GA2 instead of B or C. Thus, the constraint in this scenario is the differentiated nature of the product as well as the lack of the increased diversion based on the regulatory framework for generic substitution.

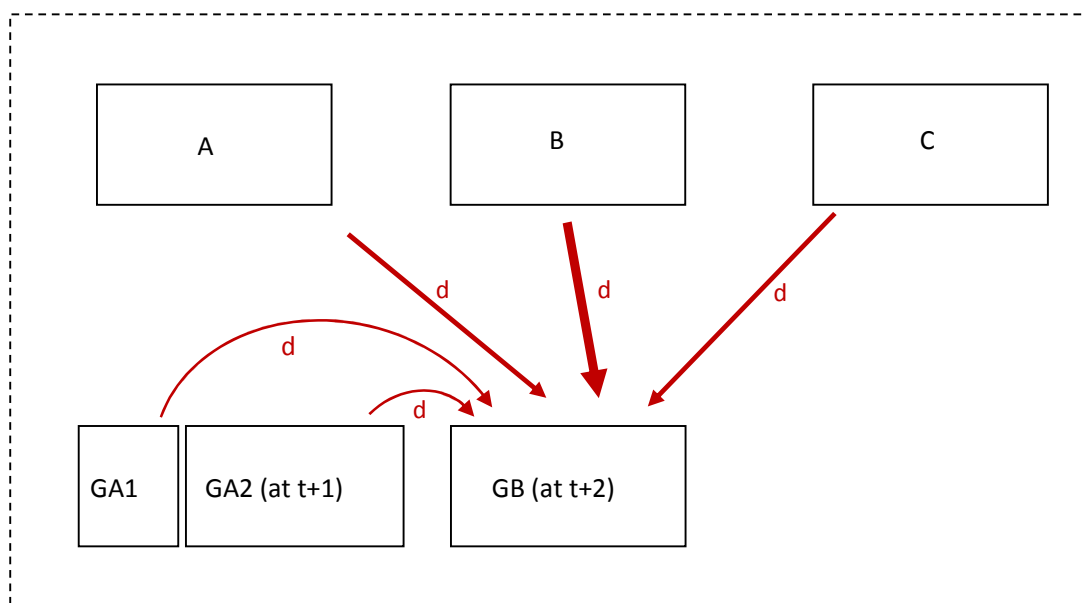


**Fig. 3: Diversion of sales after second generic entry at a 10 per cent discounted price (keeping prices for A, B, C and GA1 constant)**

In the final stage of this scenario (Fig. 4), the diversions of sales ( $d$ ) shift again with the entry of GB at the time of patent expiry for brand drug B ( $t+2$ ). This time, the highest degree of diversion is likely to occur between B and GB. Again the generic substitution regulation has a major impact on the diversion of sales from B to GB, as dispensing pharmacist can or must to also switch their customers to the cheaper generic drug. The degree of diversion from C to GB should generally be similar to the previous stage. Yet, the big diversion from GA1 to GA2 in the previous stage does not reoccur in this stage. Despite the fact that the patients regarding the GA1-GA2 switch seem to be eager to switch, which indicates either a certain degree of price sensitivity or is evidence of a stricter regulatory system based on mandatory

generic substitution, the diversion of sales from GA1 and GA2 to GB are likely to be significantly lower.

However, because of these price differentials, the important question is whether subsequent generic entrants (GA2 and GB) are able to exert competitive pressure on brand drugs (A, B and C) as well as on the existing generic drug GA1. The pharmacist cannot switch customers to GB on his own accord, despite being therapeutic substitutes.



**Fig. 4: Diversion of sales after third generic entry at a 10 per cent discounted price (keeping the prices for A, B, C, GA1, and GA2 constant)**

In conclusion, one should expect the diversion of sales from brand drugs to generic drugs once the first generic company enters the market and, as time progresses, the diversion of sales from brand drugs and generic drugs to subsequent generic entrants. The only constraint that could impair the degree of diversions from brand drugs to generic drugs, as well as from generic drugs to other generic drugs should be the drug substitution regulations in place in the relevant Member States. In particular, the first generic entrant should experience diversions of sales to a subsequent generic entrant with a generic version of the same brand drug. It would be only logical for a reasonable doctor or pharmacist to switch patients, who have already switched once, to a cheaper generic version of the same drug. There should

not be a significant first mover advantage for the early entering generic company with a corresponding positive effect on market shares compared to subsequent entrants, or at least it should not prevail.

Consequently, this hypothetical scenario would lead to the definition of a large market with a number of market players that only have a small market share. Every new entrant exerts competitive pressure on the other market players. The level of pressure is only restricted by relevant drug substitution regulations. In such a market, it would therefore be less likely for brand company A to be found dominant. The next section, however, shows that the discussed scenario is unrealistic. In fact, a generic first-mover advantage does exist and it is likely to be caused by the switching inertia of prescribing doctors and dispensing pharmacists.

#### **5.1.1.1. First-mover advantage based on prescribing inertia**

The notion discussed above, that a potential first-mover advantage of the early generic entrant would not prevail due to the competitive pressure that the other market players exert is contradicted by empirical evidence. This empirical evidence indeed shows that a first-mover advantage does exist and, in addition, can also have a significant positive impact on the market share of the early entrant as well as a negative impact on the market shares of subsequent entrants.<sup>59</sup> The evidence further suggests that the market share of the first generic entrant might not be affected as significantly by subsequent generic entry as one would expect.<sup>60</sup> While the market share of the first generic entrant remains constant or decreases just slightly, following subsequent generic entry, the market share of the second generic

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<sup>59</sup> Richard E Caves, Michael D Whinston and Mark A Hurwitz, 'Patent expiration, entry, and competition in the U.S. pharmaceutical industry' (1991) Brookings Papers on Economic Activity 1 (panel data of brand and generic prices, market shares and quantities sold for 30 drugs that lost patent protection during 1976 and 1987); Henry G Grabowski and John M Vernon, 'Brand loyalty, entry and price competition in pharmaceuticals after the 1984 Drug Act' (1992) 35 Journal of Law and Economics 331 (using panel data for 18 drugs that were first exposed to generic competition during 1983-1987); Aidan Hollis, 'The importance of being first: evidence from Canadian generic pharmaceuticals' (2002) 11 Health Economics 723. (using panel data for 31 drugs between 1995-1999 that were faced with generic competition between 1994-1997, sold in 9 Canadian provinces)

<sup>60</sup> Hollis (n 59) 729.

entrant is not only considerably smaller at the time of entry but also stays at almost the same level over the course of the proceeding three years.<sup>61</sup>

This first-mover advantage could be explained by the prescribing inertia. Prescribing doctors as well as dispensing pharmacists show a considerable inertia to switch a patient from a brand drug to a generic version or, alternatively, from one generic version to another slightly cheaper one.

There are several possible explanations for this inertia to switch patients to a newly marketed generic version of a brand drug. Prescribing doctors may wish to avoid confusing elderly patients who have taken a certain drug for a long time by prescribing then new drugs that may be of a different colour or shape drugs or even drugs in a different dosage form.<sup>62</sup> They might fear that their patients do not fit the criteria of the group of patients which were used in the bioequivalence tests and, thus, will question the new drug's effectiveness and safety for their patients.<sup>63</sup> Dispensing pharmacists have stated during interview studies that they sometimes tend not to switch patients from brand drugs to generic drugs even though they would be able to, out of tiredness having to educate suspicious and mistrusting patients about the bioequivalence of generic drugs compared to their brand counterparts.<sup>64</sup> However, such inertia can also be caused by serious doubt regarding the bioequivalence of a generic drug in relation to its brand counterpart, questioning the effectiveness and suitability of generic drugs as opposed to the brand version and the increased probability of adverse effects and life changing consequences for their patients.

This problem can be highlighted by a case study regarding the drug treatment for epilepsy. Epilepsy is a chronic neurological disorder that causes seizures. The aim of

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<sup>61</sup> Ibid.

<sup>62</sup> Peter Meredith, 'Bioequivalence and Other Unresolved Issues in Generic Drug Substitution' (2003) 25 *Clinical Therapeutics* 2885.

<sup>63</sup> Ibid. 2879.

<sup>64</sup> Liz Gill and others, 'How do customers and pharmacists experience generic substitution?' (2010) 4 *International Journal of Pharmaceutical and Healthcare Marketing* 375, 386. (interview study conducted in Australia, Italy and Finland, using unstructured interviews to explore subjective experience of 15 pharmacists and 30 customers in relation to generic substitution. The interviewees provided similar responses across the three different countries.)

the drug treatment is not to cure the disorder but to control the seizures.<sup>65</sup> If such seizures are uncontrolled, they are likely to have serious adverse effects on the patient's quality of life. Seizures can lead to loss of work time, an increase in doctor and hospital visits and possibility of severe motor vehicle accidents if they occur during travel.<sup>66</sup> To achieve optimal seizure control many patients require careful 'fine-tuning' of their medication.<sup>67</sup> Once this optimisation of the drug treatment is achieved, one should be able to assume that the same dose of a bioequivalent generic drug will have the same effect.

Yet, a number of treatment studies have shown that initially controlled patients experienced breakthrough seizures after being switched from the brand drug to a generic version or from one generic drug to another. Following a survey in which 150 neurologists participated, 30 per cent of the neurologist reported a case in which a patient had experienced a breakthrough seizure after being switched to a generic substitute of the brand anti-epileptic drug (AED).<sup>68</sup> According to the study, almost all patients (92 per cent)<sup>69</sup> were switched back to the brand AED after suffering the breakthrough seizure and 96 per cent of patients were able to regain seizure control after the switch-back.<sup>70</sup> In a separate survey 196 out of 301 neurologists reported breakthrough seizures after having patients switched to generic AED and 163 neurologists reported increased side-effects after the switch.<sup>71</sup> A further study provides evidence that patients who were admitted to hospital or treated in an emergency room following a seizure had 81 per cent greater odds of having experienced a switch from a brand AED to a generic AED within the previous

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<sup>65</sup> Meir Bialer, 'Generic Products of Antiepileptic Drugs (AEDs): Is It an Issue?' (2007) 48 *Epilepsia* 1825.

<sup>66</sup> M. J Berg and others, 'Generic substitution in the treatment of epilepsy: patient and physician perceptions' (2008) 13 *Epilepsy & Behaviour* 689; Bialer (n 65) 1830.

<sup>67</sup> B. E Gidal, 'Generic antiepileptic drugs: how good is close enough?' (2012) 12 *Epilepsy Currents/American Epilepsy Society* 32.

<sup>68</sup> M. J Berg and others, 'Generic substitution in the treatment of epilepsy: Case evidence of breakthrough seizures' (2008) 71 *Neurology* 525.

<sup>69</sup> The few patients that have not been switched back had reportedly difficulties with their insurance companies and could not switch back due to cost reasons or increased the dosage of the generic AED.

<sup>70</sup> M. J Berg and others (n 68) 526.

<sup>71</sup> Andrew N Wilner, 'Therapeutic equivalency of generic antiepileptic drugs: results of a survey' (2004) 5 *Epilepsy & Behavior* 995.

6 months.<sup>72</sup> A study also links the switch to a generic AED with an increase in daily dosage and a higher rate of utilisation of medical services such as doctor visits and hospitalisation.<sup>73</sup>

Such severe negative consequences following the switch to a generic version of a brand drug should of course not be generalised. Not all medical conditions are chronic and not every switch from a brand drug to a generic drug will lead to such adverse effects. But the case study of AEDs highlights the fact, that despite being bioequivalent, generic drugs might not have the identical attributes in terms of efficacy that the brand drug possesses and, therefore, might not be regarded as substitutes in terms of market definition. This is an issue that is not only relevant to AEDs but also holds true for all drugs. The possible negative consequences become evident in AEDs which makes them the ideal case study in which to address the general issue regarding bioequivalence and its possible association with the prescribing inertia of doctors.

Bioequivalence ensures that the generic drug is identical to the brand drug in terms of dosage form, strength, route of administration, quality and intended use.<sup>74</sup> Testing bioequivalence generally involves the measurement of area under the plasma concentration time curve (AUC) and the maximum plasma concentration (Cmax). AUC describes the drug absorption in a given time, whereas Cmax describes the maximum plasma concentration, meaning the maximum concentration the drug achieves in the tested area after the drug has been administered.<sup>75</sup> During the statistical analysis of bioequivalence the generic drug does not have to match the brand drug results to 100 per cent. The generic drug is regarded as bioequivalent if its AUC level is 90 per cent in relation to the brand drug and if its Cmax is in the acceptable range of 80 to 125 per cent. These facts can

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<sup>72</sup> W. M. Zachry and others, 'Case-control analysis of ambulance, emergency room, or inpatient hospital events for epilepsy and antiepileptic drug formulation changes' (2009) 50 *Epilepsia* 493.

<sup>73</sup> J. LeLorier and others, 'Clinical consequences of generic substitution of lamotrigine for patients with epilepsy' (2008) 70 *Neurology* 2179.

<sup>74</sup> European Medicines Agency, *Guideline on the investigation of bioequivalence* (CPMP/EWP/QWP/1401/98 Rev. 1 2008) 3.

<sup>75</sup> Jeff Evans, 'Generic and Brand-Name AEDs Bioequivalent' (2010) *Internal Medicine News* <[http://imn.gcnpublishing.com/fileadmin/content\\_pdf/imn/archive\\_pdf/vol43iss10/70514\\_main.pdf](http://imn.gcnpublishing.com/fileadmin/content_pdf/imn/archive_pdf/vol43iss10/70514_main.pdf)>.

make it necessary to differentiate bioequivalence into “drug prescribability” and “drug switchability”.<sup>76</sup> Drug prescribability refers to the scenario in which the doctor decides to prescribe a new patient a drug for the first time, choosing either a brand drug or a generic version of the drug. Drug switchability refers to a scenario in which a patient is switched from the brand drug to a generic drug, or from one generic to another.<sup>77</sup> The potential difference between prescribability and switchability can be illustrated using a simple theoretical example. In the prescribability scenario a doctor chooses between a brand drug (A) and the generic version (GA). Having established that GA is bioequivalent to A and that all the necessary requirements have been fulfilled by relying on clinical test and documentation regarding the safety and efficacy of drug A, the prescribing doctor is aware that the GA’s quality, safety and efficacy is within the above mentioned AUC and Cmax parameters – parameters which were chosen by the agencies to ensure a maximum bioequivalence between brand drugs and their generic counterparts. In the second scenario regarding the switchability, the case might be different. In this scenario the doctor can choose from brand drug (A) and two generic versions of A: (GA1) and (GA2). A has been the reference drug for both generic drugs regarding the bioequivalence. However, this fact does not necessarily provide information regarding the relationship between GA1 and GA2, which is illustrated below (Fig. 5).

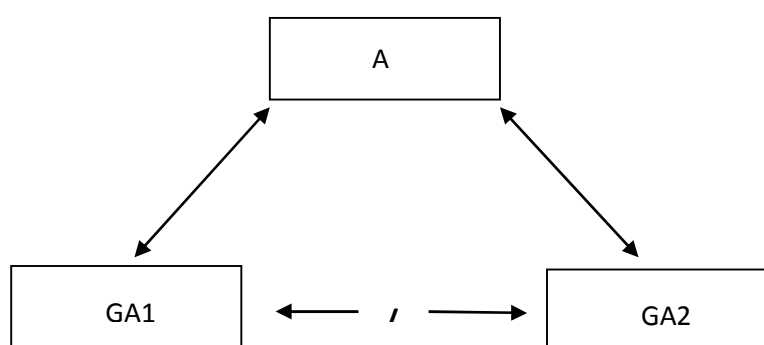


Fig. 5: Bioequivalence of drugs in relation to each other

<sup>76</sup> Dieter Hauschke and Volker W Steinijans, ‘The U.S. draft guidance regarding population and individual bioequivalence approaches: comments by a research-based pharmaceutical company’ (2000) 19 *Statistics in Medicine* 2769.

<sup>77</sup> Bialer (n 65) 1827.

GA1 and GA2 only have to be bioequivalent in relation to A. However, as has been described previously, a certain amount of acceptable variance is built in the statistical analysis of bioequivalence, i.e. the maximum plasma concentration of the generic drug can vary from 80 to 125 per cent in relation to the brand drug. In relation to each other, GA1 and GA2 could therefore show a possible variance of 45 per cent, despite being bioequivalent in relation to A. Although it has been noted that the variance in practice should not normally occur and should not differ by more than 5 to 7 per cent,<sup>78</sup> a recent study has shown that variances between generics with regard to relevant parameters can be greater than 15 per cent in a number of cases and, in some cases, even greater than 25 per cent.<sup>79</sup> The study ultimately advocates for caution when switching from one generic to another as the variance is potentially higher than following the switch from a brand drug to a generic version.<sup>80</sup> Despite the likely limitations of these studies and the comparatively small number of cases in which the experience of breakthrough seizures following a drug switch could be associated with the increased pharmacological variance between the drugs, this evidence and the discussion of the likelihood of adverse effects following the generic switch of AEDs has had a significant impact on doctors' prescribing behaviour. 88 per cent of doctors that participated in a survey study were concerned about an increase in such seizures in patients who are switched from a brand AED to a generic AED, or who are switched consistently from one generic AED to another.<sup>81</sup> 55 per cent of the doctors also were "very" or "extremely concerned" about the level of seizure control after the switch.<sup>82</sup>

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<sup>78</sup> Emilio Perucca and others, 'Recommendations of the Italian League Against Epilepsy Working Group on Generic Products of Antiepileptic Drugs' (2006) 47 *Epilepsia* 17.

<sup>79</sup> Gregory L Krauss and others, 'Assessing bioequivalence of generic antiepilepsy drugs' (2011) 70 *Annals of Neurology* 221.

<sup>80</sup> *Ibid.* 224, 225.

<sup>81</sup> M. J Berg and others (n 68) 697.

<sup>82</sup> *Ibid.*



#### 5.1.1.2. Impact of doctors' inertia on the early entry scenario

Based on the discussion above, doctors' inertia can have a significant impact on the diversion of sales from brand drugs to generic drugs. The assumption that patients who were willing to switch in the past will switch again does not necessarily hold true. As shown above using the example of AEDs, generic-to-generic switches might cause adverse effects for the patient who has already been treated with a brand drug and who has been switched to a generic drug. Switches from a brand drug to a generic version of a different brand drug are also unlikely to occur despite the fact that both brand drugs are horizontally differentiated and could be used equally to treat the same medical condition. The difference between the above outlined base-line scenario and the scenario including the effect of doctors' inertia is illustrated below (Fig. 6). Patients who were treated with brand drug (A) prior to the market entry of GA1 are likely to switch to GA1. Here, the difference compared to the previous scenario is that these patients are not likely to switch from GA1 to GA2 because of the discussed discrepancies regarding the bioequivalence between generic drugs and the associated lack of drug switchability. The same holds true for the diversion of sales from the brand drug B2 to the generic version GB1. Any diversion of sales between GA1 and GA2 to GB1 is not to be expected. The relatively small diversion of sales from A to GA2 follows from the size of the market for which GA2 is competing. The market for patients that are willing to switch to a generic drug should be smaller compared to the market for which the first entrant GA1 has competed initially.

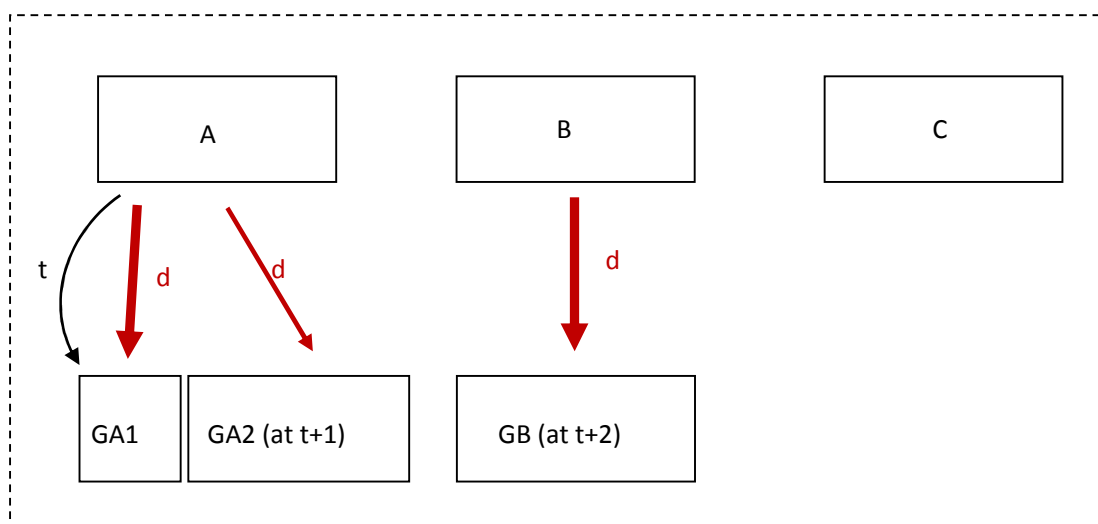


Fig. 6: Change in diversion of sales after considering doctors' prescribing inertia

Due to the distinction between drug prescribability and drug switchability and the respective prescribing behaviour of doctors in relation to “new” and previously treated “old” patients, it is necessary to have a more detailed look at this horizontally differentiated market and its mechanisms to understand the actual diversions of sales. The following analysis does not only hold true for the specific market for anti-epileptic drugs but can also be generalised, at least with regards to chronic or other long-term illnesses. (Fig. 7)

Both groups comprise the market for AEDs, but the ratio is unbalanced. “Old” patients should represent the biggest share of the market. This is due to the fact that a number of patients that have already been treated with the brand drug accumulated over the years in which no generic version of the brand drug was available at all. The smaller share of the market is represented by “new” patients who were recently diagnosed with epilepsy and need to choose their form of treatment now.

At the point of initial generic entry (GA1), the “old” patients can choose to switch to GA1 and the “new” patients can choose the brand drug (A) or GA1. Once the patients have made the choice to switch to GA1 or to use GA1 as their initial treatment, they are almost “locked in” and are no longer part of the market for which future generic entrants will be able to compete for. The analysis of the studies above has shown that patients who have switched once either stay with

their generic choice or switch back to the brand drug in case they experience breakthrough seizures following the switch. Those patients who switch back to the brand ( $A_r$ ) will not switch again and are therefore also no longer part of the market for subsequent generic entrants. The second generic entrant GA2 can therefore only compete for the remaining “old” patients who have not yet switched to GA1 and the newly diagnosed “new” patients. That said, GA2 does not necessarily only face competition from G1 but also from generic versions of other brand drugs (like GB1) that are deemed to be suitable for the initial treatment of “new” patients.<sup>83</sup>

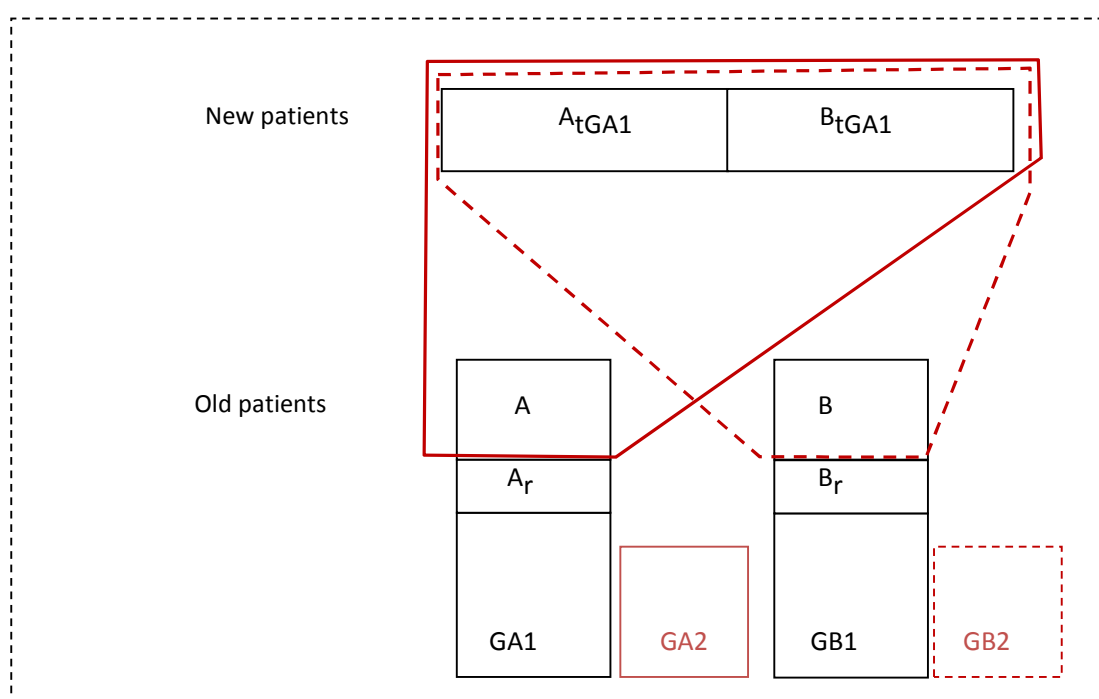


Fig. 7: Diagram highlighting contestable market for subsequent generic entrants (GA2 and GB2)

This analysis shows that the prescribing behaviour of doctors and the associated prescribing inertia can have a significant impact on the substitutability of drugs on a horizontally differentiated market. Whereas all drugs in the market are substitutable in the baseline model, the situation is far different once prescribing inertia is introduced. This is especially the case, when one generic company enters early. Before drawing general conclusions from this hypothetical definition of the

<sup>83</sup> “[The German ad hoc commission of the German Chapter of the International League Against Epilepsy] stated that generic products of gabapentin and lamotrigine can be used without problems for initial treatment of epileptic patients.” Bialer (n 65) 1825.

relevant market, the next sections examines whether the situation changes when the generic company agrees to not enter the market.

### 5.1.2. Pay for delay scenario

In this scenario, the same brand drugs (A,B and C) as in the early generic entry scenario are present in the market. They are still horizontally differentiated and can generally be used equally to treat the same medical condition. This time, however, instead of brand drug A agreeing to the early generic entry of GA prior to patent expiry, A is paying GA a lump sum of money and in return GA is agreeing to not enter the market until the patent which covers A expires. To simplify the scenario, only one generic entrant per brand drug exists.

Using the same baseline scenario as in the early generic entry case above, one would not expect patients who have been prescribed drug A to switch unless a bioequivalent and less costly alternative to drug A is available. Due to the pay for delay agreement between A and GA, the latter will not enter the market until the patent which covers A expires. However, the patients who have been prescribed A should be able to switch to GB, the generic version of brand drug B, once it enters the market. This should be possible due to the fact that GB is bioequivalent to B, which is again part of a horizontally differentiated market of drugs (A,B and C) that can all be used to treat the same medical condition. In this baseline scenario, the relevant market should thus be comprised of the brand drugs (A,B and C) and the generic versions of these brand drugs.

However, as in the early generic entry scenario above, the baseline scenario does not take the prescribing behaviour of doctors and any associated inertia into consideration, following the market definition in *AstraZeneca*. As has been shown for the early generic entry scenario, taking the prescribing behaviour of doctors into consideration in the case of a horizontally differentiated market changes the picture completely. In certain cases, the prescribing behaviour is not driven by the doctor's preferences of one drug over the other but, rather, it is driven by the doubt of the doctor regarding the actual effectiveness and suitability of the brand

drug or generic drug for their patients and the medical condition which needs to be treated.

Once more taking the market for antiepileptic drugs as an example and applying the pay for delay scenario to this market, we again see a totally different picture compared to the baseline scenario in which the prescribing behaviour has been excluded (Fig. 8). The market is again divided into “new” patients who have not yet been treated for epilepsy and the majority of “old” patients who have been treated for epilepsy for a number of years. “New” patients can be treated with any of the brand drugs or with any of the generic drugs because of the “drug prescribability” of all drugs on the market. Already treated “old” patients, however, should only switch to the generic version of the brand drug that they have been prescribed over the years, as the generic version of other brand molecules might lack “drug switchability”.

Following the structure of this horizontally differentiated market which emerged out of the prescribing behaviour of doctors in reaction to the pharmacological differences between brand drugs and their generic versions and between generic drugs themselves, a pay for delay settlement between a brand company and a generic company can have a significant impact on the market structure itself and available substitutes for the two groups of patients. With no generic version available for patients who have been treated with brand drug A for a number of years, these patients have no viable alternative to brand drug A. Even if a generic version to brand drug B enters the market, these patients will not be able to switch because of the lack of “drug switchability”. They are effectively locked-in to brand drug A. The “new” patients, who have not yet been treated, can be prescribed brand drugs A or B, as well as generic version GB once it enters the market (tGB). A pay for delay settlement between brand company A and generic company GA will thus have less of an impact on the drug choice of “new” patients. Compared to “old” patients, “new” patients at least have the opportunity to be prescribed a generic drug.

Yet what needs to be kept in mind is the imbalance of the market share between the two groups of patients. Due to the long-standing market presence of

brand drugs A and B, all patients with epilepsy had been prescribed one of these drugs until generic version GB entered the market. No patient that has been prescribed brand drug A will switch to GB. Over the years, the share of patients who are “locked in” has accumulated substantially. The only part of the market that is not captured by the pay for delay settlement between A and GA is the smaller share of newly diagnosed patients who will be treated for epilepsy for the first time. The share of this part of the market is likely to be significantly smaller than the share of treated patients which has been accumulated over several years.

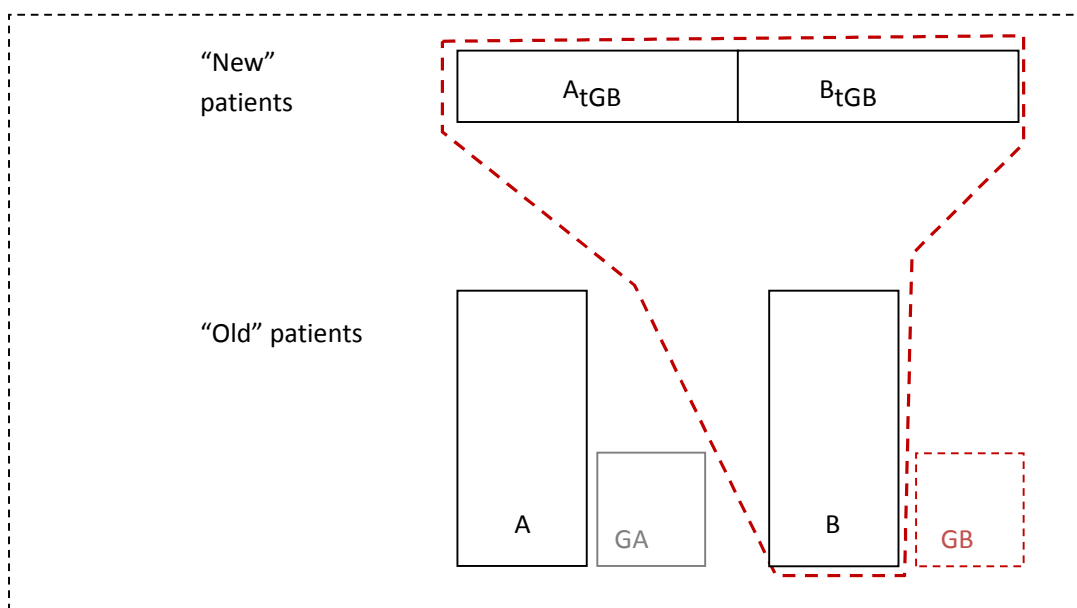


Fig. 8: Diagram highlighting the contestable market for generic entrant GB

## 5.2. Conclusion

A number of conclusions can be drawn from the application of the market definition in the *AstraZeneca* case to the hypothetical scenarios in a horizontally differentiated market. First and foremost it has to be mentioned that the actual market definition in the *AstraZeneca* judgment should only be used to provide limited guidance for future investigations. This is unfortunate, as it is the first and to-date only published market definition in the field of European pharmaceutical antitrust. In particular, the European Commission’s finding that doctors’ prescribing inertia should be regarded as exogenous should not be generalised. Although this finding has enabled the Commission to define the relevant market rather narrowly

and subsequently find AstraZeneca dominant, the finding should not be applied to horizontally differentiated markets such as the one in the hypothetical analysis. As has been shown in the analysis of the two scenarios, doctors' prescribing inertia based on the uncertainty of a drug's effectiveness and potential side-effects can be a key factor for the appropriate definition of the relevant market. The failure to endogenise doctors' inertia could lead to artificial market being defined, which potentially increases the likelihood of Type I or Type II errors depending on market characteristics. The failure to endogenise inertia in vertically differentiated markets as in *AstraZeneca* can lead to markets being defined too narrowly and thus to over-enforcement and Type I errors. Whereas additionally, in horizontally differentiated markets - like the one in the hypothetical scenario - the failure to endogenise leads to the definition of overly broad markets and therefore to under-enforcement and potential Type II errors.

## **6. The General Court's finding regarding the first abuse**

Having discussed the General Court's findings in relation to AstraZeneca's appeal of the European Commission's market definition and having extended the analysis of the Court's key finding to a hypothetical market for antiepileptic drugs, this section addresses AstraZeneca's plea in its appeal with regard to the first abuse. The section starts by addressing the General Court's finding of abuse and, following a detailed comparative legal analysis of US Walker Process Doctrine and the General Court's approach. This analysis shows that it was correct to dismiss AstraZeneca's plea that the European Commission finding of an abuse in relation to the submission of misleading information to a patent office was overly restrictive compared to the US Walker Process Doctrine. In doing so, the analysis goes beyond the actual discussion of the abuse. However, in contrast to the previous section that highlights the lack of guidance that can be drawn from the *AstraZeneca* judgment with regards to market definition, this section uses the *AstraZeneca* judgment and the process leading up to it as a case study to showcase more generally the need for careful comparative legal analysis in the field of pharmaceutical antitrust. This

result has important implications for the analysis of European pay for delay settlements in the subsequent chapter.

In its judgment the General Court has found that it amounts to an abuse to submit

*‘to the public authorities misleading information liable to lead them into error and therefore to make possible the grant of an exclusive right to which an undertaking is not entitled, or to which it is entitled for a shorter period’.*<sup>84</sup>

For this finding the Court relied upon the longstanding definition of exclusionary abuse stemming from the Court of Justice’s judgment in *Hoffmann-la Roche v Commission*, defining it as

*‘an objective concept relating to the behaviour of an undertaking in a dominant position which [influencing] the structure of the market [and] has the effect of hindering the maintenance of the degree of competition still existing in the market or the growth of that competition.’*<sup>85</sup>

The General Court then went on to refer to the special responsibility of a dominant company *‘not to allow its conduct to impair undistorted competition on the market’*,<sup>86</sup> meaning that certain types of conduct that are legitimate for non-dominant companies might be considered as abusive, in the sense of Art. 102 TFEU, for dominant companies.

Stating that this type of conduct is eliminating a competitor and thereby strengthening its position by using methods other than those which come within the scope of competition on the merits,<sup>87</sup> the Court further found that AstraZeneca’s special responsibility not only disallows the company to provide

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<sup>84</sup> *AstraZeneca v European Commission* [2010] (n 2) 355.

<sup>85</sup> *Hoffmann-La Roche & Co. AG v Commission* [1979] ECR 461, 91.

<sup>86</sup> *NV Nederlandsche Banden Industrie Michelin v Commission* [1983] ECR 3461, 57.

<sup>87</sup> *AstraZeneca v European Commission* (n 2) 354.



misleading information to the public authorities but also obliges the dominant undertaking to inform the public authority of circumstances that might have led to the wrongful granting of an exclusive right even if these circumstances come to the attention of the dominant company after the right has been granted.<sup>88</sup>

With regard to the degree of misrepresentation the Court decided that the misrepresentation does not have to be intentional to constitute an abuse due to the objective nature of the abuse.<sup>89</sup> In fact, the question, which needs to be answered, is whether the public authority has created a regulatory obstacle to competition, based on wrong or partial information. Although the concept of abuse follows a primarily objective standard, the General Court found that intention and bad faith of the submission of misleading information can nonetheless be considered as a relevant factor by the Commission.<sup>90</sup>

Furthermore, the Court dismissed AstraZeneca's argument that its conduct in question could not be deemed abusive due to a lack of enforcement of the SPC. First of all, intellectual property rights are presumed to be valid. It is assumed that such rights, which are granted by a public authority after examination, are lawful and have to be respected by competitors. Thus 'the mere possession of such an exclusive right results in keeping competitors away'.<sup>91</sup> Secondly, such a requirement would limit the application of Art. 102 TFEU. The enforcement of Art. 102 would be made conditional. Starting from the presumption of validity, the competitor would need to infringe the exclusive right to be able to challenge the alleged anti-competitiveness. Moreover, the possibility of the public enforcement of such conduct would be dependent on private infringement of the right by a competitor.<sup>92</sup>

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<sup>88</sup> Ibid. 358.

<sup>89</sup> Ibid. 356 "*proof of a deliberate nature of the conduct and of the bad faith of the undertaking in a dominant position is not required for the purpose of identifying an abuse of a dominant position.*"

<sup>90</sup> Ibid. 359.

<sup>91</sup> Ibid. 362.

<sup>92</sup> Ibid. 362.

### 6.1. The dismissal of AstraZeneca’s comparative argument – An exemplar of careful comparative analysis

In its judgment, the General Court rejected AstraZeneca’s comparative argument in a single paragraph stating that

*‘with respect to the [AstraZeneca’s] arguments based on United States law, [it] suffices to note that the position adopted by the latter cannot take precedence over that adopted by European Union law’.*<sup>93</sup>

Just as in the case of the discussion of the relevant market definition above, this situation begs more general questions.

Were the EU courts right to reject AstraZeneca’s comparative argument? Or should the Courts have drawn from the extensive expertise of the US jurisprudence<sup>94</sup> with regard to the submission of misleading information to the patent office and its antitrust treatment?

It is important to derive an answer to these questions and this can be done by way of a detailed comparative legal analysis. Although the analysis provides an answer to the question of whether the General Court’s approach to AstraZeneca’s conduct in front of the patent offices is overly restrictive to the US approach which relies on the Walker Process Doctrine, its significance for future investigations lies in the process of the comparative legal analysis itself. The analysis shows that one should refrain from prematurely applying concepts and rationales that have been developed in other jurisdictions, even - or rather especially - if the investigated

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<sup>93</sup> Ibid. 138; Interestingly, the ECJ has made no reference to US case law in its findings despite AstraZeneca’s appeal putting forward the same line of argument as in front of the General Court. *AstraZeneca v European Commission* [2012] (n 2).

<sup>94</sup> Over the last 45 years an extensive body of case law and expertise has been developed by lower US courts. See *Korody-Colyer Corp. v. General Motors Corp.* 828 F.2d 1572 (C.A.Fed.1987); *Cygnus Therapeutics Systems v. ALZA Corp.* 92 F.3d 1153 (C.A.Fed.1996).; *Nobelpharma AB v. Implant Innovations, Inc.* 141 F.3d 1059 (C.A.Fed.1998); *Unitherm Food Sys. Inc. v Swift-Eckrich, Inc.* 375 F.3d 1341 (C.A.Fed.2004); *Hydril Co. LP v. Grant Prideco LP* 474 F.3d 1344 (C.A.Fed.2007); *Dippin' Dots, Inc. v. Mosey* 476 F.3d 1337 (CA. Fed 2007); *FMC Corp. v. Manitowoc Co. Inc.* 654 F.Supp. 915 (N.D.Ill.1987); *Professional Real Estate Investors, Inc. v. Columbia Pictures Industries, Inc.* 508 U.S. 49 (1993).

conduct is similar. In this respect, the following analysis can be seen as a cornerstone for the analyses in the subsequent chapters of this thesis.

Following the detailed analysis of the Walker Process Doctrine, it will be shown in two stages that (1) the *AstraZeneca* judgment is not comparable with this doctrine due to the underlying principles of antitrust policy in the context of private patent litigation in US antitrust enforcement, and (2) that the public antitrust enforcement policy of the Federal Trade Commission (FTC), as the more comparable US enforcement policy, would (in a hypothetical scenario) be likely to come to a similar conclusion to the EU courts' findings, if it would have investigated AstraZeneca's conduct in Europe.

For the purposes of this analysis, section 6.1.1 provides a detailed explanation of the Walker Process Doctrine and its necessary requirements, before section 6.1.2 shows that the US doctrine and the General Court's judgment should not be compared. Section 6.1.3 then identifies the FTC's public antitrust enforcement policy as the appropriate policy for comparison, followed by a detailed examination of the prerequisites for the launch of an antitrust investigation into the type of conduct concerned in *AstraZeneca*. Section 6.1.4 undertakes a hypothetical application of the facts of *AstraZeneca* to the prerequisites for an FTC investigation. Based on the finding of this analysis, section 6.1.5 concludes by advocating for greater caution when undertaking comparative legal analyses in the field of antitrust, as similar conduct on both sides of the Atlantic does not necessarily have similar anticompetitive potential.

### **6.1.1. The Walker Process Doctrine in the US jurisprudence**

The Walker Process Doctrine which has been developed by the US Supreme Court,<sup>95</sup> enables the defendant in a patent infringement lawsuit to counter-attack the plaintiff using the antitrust laws. The Supreme Court held that a patent infringement lawsuit, since it is based on a patent obtained by 'fraud', could give

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<sup>95</sup> *Walker Process Equipment* (n 43).

rise to an antitrust infringement lawsuit of the patent infringement defendant against the plaintiff. The Walker Process claim is thus mostly used as an antitrust counterclaim in private patent litigation.<sup>96</sup> In essence, the Walker Process Doctrine deprives the patent owner of its limited exception of section 2 of the Sherman Act<sup>97</sup> because of the fraudulent acquisition of the patent in question. The following paragraph provides a theoretical description of the circumstances under which the Walker Process Doctrine can be sought by the patent infringement defendant.

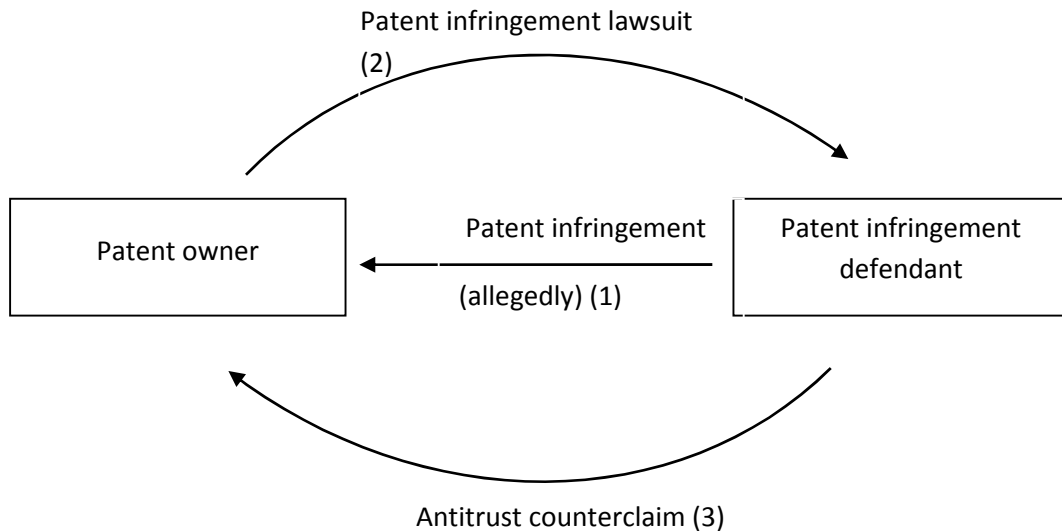
Imagine a patent owner is suing an alleged patent infringer for patent infringement. If the defendant in this infringement lawsuit perceives the patent in question to be invalid, he might decide to bring a counterclaim arguing that the patent owner is constraining competition due to his invalid patent<sup>98</sup> and therefore might be liable for antitrust infringement. In such a Walker Process counterclaim, the patent infringement defendant is arguing that the patent which is held by the patent owner is invalid because of its fraudulent acquisition. For such a counterclaim to be successful the patent infringement defendant must not only show that the patent owner has acquired the patent through fraudulent conduct in front of the United States Patent and Trademark Office (USPTO), but also that the patent owner has enforced the patent with exclusionary intent.

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<sup>96</sup> The focus in this section will lie on case law, as the academic literature is limited. Herbert J Hovenkamp, 'The Walker Process Doctrine: Infringement Lawsuits as Antitrust Violations' (2008) University of Iowa Legal Studies Research Paper No. 08-36; Christopher R. Leslie, 'Patents of Damocles' (2008) 83 Indiana Law Journal 133. Additionally a number of practitioners have contributed to the subject, writing case notes on new judgments referring to the doctrine. Robert A. Matthews, Jr, 'A primer on US antitrust claims against patentees under Walker Process' (2007) Journal of Intellectual Property Law & Practice 657; BD Daniel, 'Walker Process Proof: The Proper Prescription' (2009) 41 Rutgers Law Journal 105.

<sup>97</sup> As a general rule, private actors are immune from antitrust liability, if they petition the government, even if that petitioning has anticompetitive effects. The filing of patent application to the US Patent and Trademark Office is regarded as such a petition to the government. However, this antitrust immunity is waived if the petition is a sham or if the patent infringement defendant can successfully prove the requirements for the Walker Process Doctrine. Herbert Hovenkamp and others, *IP and antitrust: An analysis of antitrust principles applied to intellectual property law* (2nd edn, Wolters Kluwer Law & Business; Austin, 2010) §11.2b; This general rule is referred to as the *Noerr-Pennington Doctrine* and is explained in detail *infra* sec. 6.1.3.1.

<sup>98</sup> A patent gives its owner the right to legally exclude competitors from manufacturing and marketing the product which is covered by the patent. Without this right such a practice could warrant antitrust scrutiny.



**Fig. 9: The Walker Process Doctrine**

Generally speaking, every patent owner can defend his patent by challenging a potential infringer in a patent infringement lawsuit. The patent owner is also entitled to notify the customers of the alleged infringer about these circumstances. As a result of receiving this information, they might cease their business relationship with the alleged infringer. This also holds true for monopolists.<sup>99</sup> Thus the patent owner can legally use his patent to raise barriers to entry in the market. He might also use his patent to exclude competitors directly, or even indirectly, by threatening the competitor's customers which could lead to the competitor's exit – a type of conduct which could violate the antitrust laws. The first legal consequence of a successfully litigated Walker Process claim is that the patent owner is deprived of this kind of immunity from the antitrust laws – the enforcement of a patent with exclusionary intent does not normally allow for antitrust scrutiny. However, success in the first stage of a Walker Process claim does not necessarily lead to immediate antitrust liability for the patent infringement plaintiff. In the next step, the initial patent infringement defendant has the burden of proving all prerequisites necessary for a section 2 Sherman Act violation. A Walker Process counterclaim therefore consists of two parts: (1) the necessity to prove the fraudulent acquisition

<sup>99</sup> Hovenkamp (n 96) 1.

and enforcement of a patent which, if successful, deprives the patent owner of its antitrust immunity; and (2) the proof of all elements for an antitrust violation. Success in part one is by no means an indicator for success in part two. This is highlighted by the Court of Appeals of the Federal Circuit, which stated that ‘the fraudulent acquisition of the asserted patent strips the Walker Process defendant of its antitrust immunity, but that is the beginning, not the end, of the inquiry’.<sup>100</sup> In *Unitherm Food Sys., Inc. v Swift-Eckrich, Inc.* the Court of Appeals of the Federal Circuit found that Unitherm had successfully shown that the patent owner had obtained the relevant patent by fraud, but the company failed to prove the necessary elements for an antitrust violation and the Court therefore dismissed the antitrust counterclaim.<sup>101</sup>

The remainder of this section will focus on the specific requirements that need to be satisfied for a successful Walker Process claim; namely, (1) patent procurement by fraud, (2) the necessity of enforcement, and (3) the separate antitrust requirements following section 2 of the Sherman Act.

#### **6.1.1.1. Patent procurement by fraud**

Walker Process fraud is established if it can be shown independently by clear and convincing evidence that the misrepresentation or omission in front of the USPTO was material<sup>102</sup> and that the patent applicant acted with deceptive intent<sup>103</sup>.<sup>104</sup> This is the case if a patent would not have been issued by the USPTO “but for” the misrepresentation or omission.<sup>105</sup> For example,

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<sup>100</sup> *Dippin' Dots, Inc. v. Mosey* (n 94) 1348.

<sup>101</sup> *Unitherm Food Sys. Inc. v Swift-Eckrich, Inc.* (n 94) 1363.

<sup>102</sup> Following the ‘reasonable examiner test’ there must be a substantial likelihood that a reasonable examiner would have considered the omitted reference or false information important in deciding whether to allow the application to issue as a patent. *American Hoist & Derrick Co. v. Sowa & Sons, Inc.* 725 F.2d 1350 (C.A.Fed.1984) 1362.

<sup>103</sup> Such intent is warranted where the patent applicant acted grossly negligent, in other words where he knew or should have known that the withheld information would be material for consideration of the patent application by the USPTO. *Takeda Pharmaceutical Co. Ltd. v. Teva Pharmaceuticals USA, Inc.* 542 F. Supp. 2d 342 (D. Del. 2008).

<sup>104</sup> *Dippin' Dots, Inc. v. Mosey* (n 94) 1348.

<sup>105</sup> *FMC Corp. v. Manitowoc Co. Inc.* (n 94) 936.

*“for an omission such as a failure to cite a piece of prior art to support a finding of Walker Process fraud, the withholding of the reference must show evidence of fraudulent intent. A mere failure to cite a reference to the [US]PTO will not suffice.”*<sup>106</sup>

The Walker Process Doctrine should not be confused with the doctrine of inequitable conduct.<sup>107</sup> The inequitable conduct defence renders a patent unenforceable, even though it might be valid and infringed, if it can be established by clear and convincing evidence that: (1) the omitted or false information was material to the patentability of the invention; (2) the applicant had knowledge of the existence and materiality of the information; and (3) the applicant intended to deceive the US Patent and Trademark Office.<sup>108</sup> Further it was recognised that:

*‘questions of “materiality” and “culpability” are often interrelated and intertwined, so that a lesser showing of the materiality of the withheld information may suffice when an intentional scheme to defraud is established, whereas a greater showing of the materiality of withheld information would necessarily create an inference that its nondisclosure was “wrongful.”’*<sup>109</sup>

In other words, inequitable conduct could still be established even if a case shows hardly any evidence for intent, as long as it provides very convincing evidence for materiality and vice versa. However, the use of such a “sliding scale” for the degree of evidence for intent and materiality with regard to inequitable conduct was eliminated by the Federal Circuit in 2011, narrowing the standard of proof for inequitable conduct.<sup>110</sup> Although one might argue that heightened standard of

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<sup>106</sup> *Nobelpharma AB v. Implant Innovations, Inc.* (n 94) 1071.

<sup>107</sup> This is a defence in US patent law which if granted renders a patent unenforceable even though it might be valid and infringed based on the fact that the patent has been fraudulently acquired from the USPTO.

<sup>108</sup> *Takeda Pharmaceutical Co. Ltd. v. Teva Pharmaceuticals US* (n 103).

<sup>109</sup> *Digital Equipment Corp. v. Diamond* 653 F.2d 701 (C.A.Mass. 1981) 716.

<sup>110</sup> *Therasense v. Becton, Dickinson and Co.*, 649 F.3d 1276, 1286 (Fed. Cir. 2011) *“this court now tightens the standards for finding both intent and materiality in order to redirect a doctrine that has been overused to the detriment of the public.”*

proof for inequitable conduct might risk the conflation of the patent defence with the antitrust liability, the relevant standard of proof materiality is still different. Whereas the relevant standard of proof for the Walker Process Doctrine is a pure “but for” materiality, the standard of proof for inequitable conduct has been described as “but for plus”, as the Federal Circuit has recognised an exception in cases of ‘*affirmative egregious misconduct, such as the filing of an unmistakably false affidavit*’.<sup>111</sup> As a result, misconduct can be material for inequitable conduct purposes but still not give rise to Walker Process liability, ultimately keeping the patent defence and the antitrust liability as separate and distinct legal doctrines.<sup>112</sup> This difference can be explained by the different legal remedies which are sought by inequitable conduct and a Walker Process claim. Inequitable conduct is a defensive remedy which has the aim of rendering a patent unenforceable.<sup>113</sup> It is a more inclusive concept which can encompass types of conduct that fall short of fraud and therefore constitute a lesser offence.<sup>114</sup> A Walker Process claim aims to find an antitrust violation and ultimately a possible treble damages claim. This difference between the thresholds for the finding of inequitable conduct and for a Walker Process claim has repeatedly been highlighted by the courts have stated that the former is used as a “shield” in patent litigation, whereas the latter is used as a “sword”.<sup>115</sup>

#### 6.1.1.2. Enforcement

In *Walker Process* the US Supreme Court concluded that an antitrust counterclaim is only viable as long as the patent infringement plaintiff attempts to enforce a patent which was obtained by fraud.<sup>116</sup> A fraudulently procured patent alone, without any effort of enforcement, cannot serve as a foundation of a

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<sup>111</sup> Ibid. 1292.

<sup>112</sup> Christopher R Leslie, ‘Antitrust, Inequitable Conduct and the Intent to Deceive the Patent Office’ (2011) 1 UC Irvine Law Review 324, 344.

<sup>113</sup> Hovenkamp et al (n 96) §2-32.

<sup>114</sup> *Nobelpharma AB v. Implant Innovations, Inc.* (n 94) 1069.

<sup>115</sup> *Korody-Colyer Corp. v. General Motors Corp.* (n 94) 1578.

<sup>116</sup> *Walker Process Equipment* (n 42) 174.



monopolisation case.<sup>117</sup> However, filing a lawsuit against the alleged infringer is not the minimum level of enforcement. Academics have discussed whether the simple assertion of a patent and the subsequent warning of a potential competitor not to enter the market which is covered by the patent could still constitute a form of enforcement justifying a Walker Process claim.<sup>118</sup>

In 2007, the Court of Appeals for the Federal Circuit extended the minimum level of enforcement by ruling that threatening customers of the alleged patent infringer with patent litigation fulfils the enforcement requirement.<sup>119</sup> The Court thus broadened the enforcement requirement significantly and no longer regards only direct enforcement against the alleged infringer as sufficient, but also enforcement conduct that is directed against third parties that is still likely to have the same effect.

#### **6.1.1.3. Antitrust requirements**

Inasmuch as a successful Walker Process claim strips the patent owner of the above-mentioned antitrust immunity, the patent infringement defendant must prove that the plaintiffs had market power at the time of the conduct in front of the USPTO and that this conduct constitutes an act of monopolisation or the attempt to monopolise. The finding of a fraudulently obtained patent does not automatically constitute such an infringement of the antitrust laws. Establishing monopolisation or the attempt to monopolise under section 2 of the Sherman Act makes it necessary to appraise the exclusionary power of the illegal patent claim in terms of the relevant market for the product involved.<sup>120</sup>

The exclusionary conduct is normally based on the filing of an infringement lawsuit regarding the fraudulently obtained patent by the patent owner; but it can also be based on other conduct, such as the sending of threatening letters to customers. Regardless of the type of exclusionary conduct, the behaviour must be

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<sup>117</sup> *Cygnus Therapeutics Systems v. ALZA Corp* (n 94) 1161.

<sup>118</sup> *Hovenkamp* (n 95)10.

<sup>119</sup> *Hydril Co. LP v. Grant Prideco supra* (n 94)1350. Prior to this judgment the filing of a patent infringement lawsuit was necessary.

<sup>120</sup> *Walker Process Equipment* (n 94) 177.

evaluated as of the time it is asserted.<sup>121</sup> To establish exclusionary conduct, it has to be proven that the conduct is reasonably capable of creating, enlarging or prolonging monopoly power by impairing the opportunities of rivals.<sup>122</sup> The exclusionary force of the conduct must therefore be evaluated for its effect on price and output in an accurately defined antitrust market.<sup>123</sup>

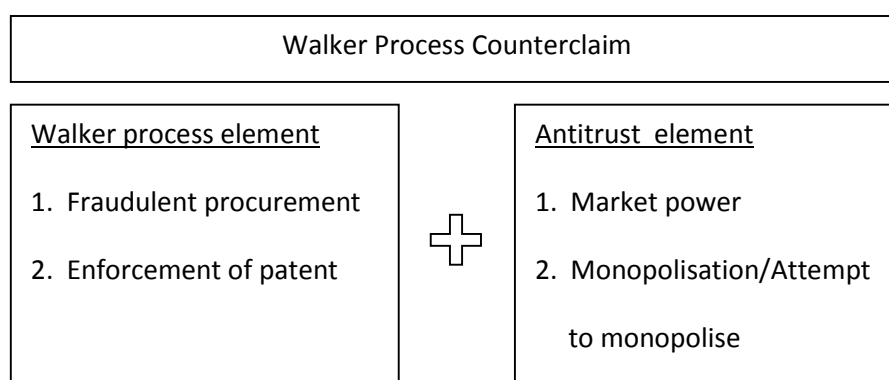


Fig. 10: The Walker Process requirements

Having explained the Walker Process Doctrine, its requirements and its usage as an antitrust counterclaim in private patent litigation, and keeping in mind the General Court's finding in relation to AstraZeneca's abuse of its dominant position by providing misleading information to patent offices, the following section turns to the discussion of whether the US doctrine and the European approach are in fact comparable.

### 6.1.2. Incomparability of the *AstraZeneca* judgment and the Walker Process

#### Doctrine

Drawing from the discussion of the General Court's judgment and the Walker Process Doctrine, the European approach and the US approach seem to be contradictory in several aspects. The US approach requires a fraudulent acquisition of the exclusive right, the enforcement of the right to overcome the antitrust

<sup>121</sup> Hovenkamp (n 95) 3.

<sup>122</sup> Herbert J Hovenkamp, "Exclusion and the Sherman Act" (2005) 72 The University of Chicago Law Review 147, 148.

<sup>123</sup> Hovenkamp (n 95) 3.

immunity and for the plaintiff to then prove a separate antitrust infringement. Europe does not require intent, bad faith, or enforcement. The European Commission has only to prove the abuse of a dominant position without having to overcome an antitrust immunity. On the face of it, the comparative argument of AstraZeneca's counsel and its criticism of the judgment might seem legitimate.<sup>124</sup> Yet, if a comparison is to lead to robust comparative results, it is essential to start from a common ground.

As discussed above, a Walker Process claim is based on an antitrust counterclaim in a private patent infringement lawsuit, whereas AstraZeneca's infringement of Art. 102 TFEU for the abuse of its dominant position was publicly enforced by the European Commission and upheld by the EU courts. This is not simply a different choice of enforcement but, rather, the root of the incomparability of the two regimes. Successful private antitrust enforcement in the US entitles the plaintiff to the award of treble damages,<sup>125</sup> which have generally been used as an incentive for private enforcement<sup>126</sup> as well as a means of compensation and for the achievement of deterrence.

However, the award of treble damages also has a significant impact on not only procedural antitrust law but on its substantive side. The possible over-compensation presented by treble damages warrants the courts in the US to ensure that only viable antitrust claims, that have an adverse effect on competition, are successfully litigated. It could therefore be argued that the US courts over the last few decades have inadvertently heightened the substantive standards regarding antitrust litigation due to concerns about over-deterrence. As a consequence, they have actually limited the likelihood of successful antitrust damages actions.<sup>127</sup> This phenomenon has already been described in 1985 by Stephen Calkins as 'equilibrating tendencies', arguing that the award of treble damages has led not

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<sup>124</sup> Murphy (n 43).

<sup>125</sup> 15 U.S.C. §15.

<sup>126</sup> Donald I Baker, 'Revisiting History - What Have We Learned about Private Antitrust Enforcement That We Would Recommend to Others' (2003) 16 *Loyola Consumer Law Review* 379.

<sup>127</sup> Leon Greenfield and David Olsky, 'Treble damages: To what purpose and to what effect?' (British Institute of International and Comparative Law, *International Cartels – Comparative Perspectives on Practice, Procedure and Substance*, London, February 2007) 13.

only to higher substantive standards but also to an adjustment of procedural standards, such as proof of damages and standing to accommodate for the potential over-deterrence following the award of treble damages.<sup>128</sup> According to William E. Kovacic,

*‘A court might seek to correct the perceived infirmities in the antitrust system by recourse to means directly within its control – namely by modifying doctrine governing liability standards or by devising special doctrinal tests to evaluate the worthiness of private claims.’<sup>129</sup>*

Indeed, the US Supreme Court in *Walker Process* was also driven by the urge to equilibrate the legal standards with the potential gains from litigation for the patent infringement defendant filing a Walker Process counterclaim, when Justice Harlan stated that the heightened standard for deliberate fraudulent procurement compared to the one for inequitable conduct is necessary in the light of a Walker Process claim.<sup>130</sup> This underlying rationale is enshrined in the subsequent case law by the Court of Appeals for the Federal Circuit. The Court repeatedly stated that the inequitable conduct standard is a shield in patent litigation whereas a Walker Process claim is a sword. Reversing this argument, the legal standards of proof for a Walker Process claim could be lower in the absence of the potential for treble damages.

Based on these findings, it cannot be established whether the European Commission’s requirements for the finding of abuse, which were upheld by the General Court and the ECJ, are overly restrictive compared to the requirements set

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<sup>128</sup> Steven Calkins, ‘Summary judgment, motion to dismiss, and other examples of equilibrating tendencies in the antitrust system’ (1985) 74 *Georgetown Law Journal* 1065, 1080, 1100.

<sup>129</sup> William E Kovacic, ‘Private participation in the enforcement of public competition laws’ in Mads Andenas, Michael Hutchings and Philip Marsden (eds), *Current competition law Vol.II* (British Institute of International and Comparative Law, London 2004) 174.

<sup>130</sup> private actions could reach monopolies “*practiced under patents that for one reason or another may turn out to be voidable under one or more of the numerous technicalities attending the issuance of a patent, [and] might well chill the disclosure of inventions through the obtaining of a patent because of fear of the vexations or punitive consequences of treble-damage suits.*” *Walker Process Equipment* (n 42) 180.

out by the Walker Process Doctrine.<sup>131</sup> Such a comparison cannot lead to robust results, as the origin for the differences in the legal standards concerning the Walker Process Doctrine are rooted in the underlying principles that are unique to the US jurisprudence. AstraZeneca's comparative argument is thus not a valid one. However, this finding does not provide an answer to the more general question of whether the General Court's judgment and approach to the anticompetitive misuse of procedural rights is overly restrictive in comparison to US antitrust enforcement. For this reason the judgment needs to be compared to a US antitrust enforcement policy that is more comparable, namely the public antitrust enforcement policy of the Federal Trade Commission (FTC).

The following section first sets out the reason for the comparison with the FTC Act. It then identifies the FTC's enforcement policy concerning the conduct of misrepresentation in front of governmental agencies and the necessary requirements for FTC investigations. These requirements have been set out in two previous investigations against Bristol Myers-Squibb and Union Oil Company of California. In the final part of the section, the facts of the *AstraZeneca* case are applied to the previously identified FTC requirements so that it can be established whether the FTC would have been able to hypothetically launch an investigation into AstraZeneca's behaviour, scrutinising the anticompetitive potential of AstraZeneca's conduct.

### **6.1.3. Comparison to the public enforcement policy of the Federal Trade Commission**

The public antitrust enforcement policy of the FTC offers a much more feasible ground for comparison with the *AstraZeneca* judgment compared to the private antitrust enforcement following section 2 of the Sherman Act. Although the FTC has the power to publicly enforce conduct based on the violation of section 2 of the

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<sup>131</sup> See Kovacic (n 129) 176, 77 (arguing that EU competition policy has different liability standards and is more interventionist because of reduced private rights of action and the lack of treble damages).

Sherman Act,<sup>132</sup> it can also base its enforcement activities on section 5 of the FTC Act. This provides it with the means to prosecute “*unfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce*”,<sup>133</sup> enabling the FTC to scrutinise at least the same types of conduct as private parties using section 2 of the Sherman Act, yet lacking a provision awarding treble damages.<sup>134</sup> The use of section 5 of the FTC Act could therefore address the court’s fear about the over-deterrence in private litigation, which spurs the felt need to adjust the liability standards as mentioned above.<sup>135</sup> These procedural traits make the FTC Act more comparable to the General Court’s judgment in *AstraZeneca*. The comparison is not only based on two public enforcement regimes, but the FTC is also able to address the issue of possible anti-competitive conduct following the submission of misleading information to public authorities without having to comply with the high standards of proof of the Walker Process Doctrine, as this doctrine is only of concern following the private antitrust enforcement of section 2 of the Sherman Act.

However, the FTC is constrained in its enforcement efforts by the previously mentioned Noerr-Pennington Doctrine, which bars certain behaviour from antitrust scrutiny. Before this section turns to the actual enforcement activities and the necessary requirements for a hypothetical investigation of AstraZeneca’s conduct under section 5 of the FTC Act, it briefly explains the characteristics of the Noerr-Pennington Doctrine itself.

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<sup>132</sup> To the knowledge of the author the FTC has not legally challenged any unilateral conduct based on the theory of violation of Sec 2 of the Sherman Act in relation to question whether the submission of misleading information to public authorities would be barred from the antitrust rules.

<sup>133</sup> Commissioner Leibowitz has noted that ‘*Section 5 was intended from its inception to reach conduct that violates not only the antitrust laws, but also the policies that those laws were intended to promote [...] such as innovation.*’ Also stating that ‘*deceitful conduct has fallen within the Section 5’s province for effects on competition from the FTC’s earliest days.*’ Jon Leibowitz, *Concurring opinion of Commissioner Leibowitz in the matter of Rambus, Inc.: Docket No. 9302* <<http://www.ftc.gov/os/adjpro/d9302/060802rambusconcurringopinionofcommissionerleibowitz.pdf>> 1.

<sup>134</sup> Section 5 of the FTC Act was designed to have a broader scope than the Sherman Act and the Clayton Act enabling the FTC also to prosecute types of conduct which are not or not yet covered by these two acts, filling the gaps in antitrust enforcement.

<sup>135</sup> William E Kovacic and Marc Winerman, ‘Competition policy and the application of section 5 of the Federal Trade Commission Act’ (2010) 76 *Antitrust Law Journal* 929, 939. (also arguing that section 5 FTC Act might supply a means of avoiding the pitfalls that judges associate with the litigation of private antitrust disputes in the federal courts) at 947.

### 6.1.3.1. Noerr-Pennington Doctrine

According to this doctrine any petition by an American citizen to the government should fall outside the scope of antitrust scrutiny.<sup>136</sup> Generally speaking, the doctrine is based on the First Amendment of the US Constitution which states that “*Congress shall make no law [...] abridging [...] the right to petition the government for a redress of grievances*”. In other words, every citizen shall be free to “*inform their representatives in government of their desires with respect to the passage or enforcement of laws*”.<sup>137</sup> This freedom does not only include the legislative process but also petitions to government agencies even with the sole intention of hindering competitors entering the market or of eliminating competition completely.<sup>138</sup> The notion behind this doctrine is that the private entity itself is not engaging in anti-competitive conduct. Rather, the private entity is asking either the government to enact legislation in its favour or for a governmental agency to decide or rule in its favour, which might have anti-competitive effects. In both cases, the potential anti-competitive effect results from the governmental action. The US Supreme Court was concerned that the governmental decision-making process would be impeded, or at least rendered less efficient, if the citizens were not able to bring such petitions freely.<sup>139</sup> This freedom would be undermined if antitrust laws were applicable in this context. The antitrust laws should only regulate business activity and not indirectly regulate political decisions.<sup>140</sup> Private parties shall be able to put forward any proposal and leave it to the government to make a decision. Yet this antitrust immunity is not unlimited. Actions should not be covered by this antitrust immunity if they are “*ostensibly directed toward influencing governmental action [so that this] is a mere sham to cover what is actually nothing more than an attempt*

<sup>136</sup> *Eastern Railroad Presidents Conference et al. Petitioners, v. Noerr Motor Freight, Inc. et al.* 365 U.S. 127 (1961) “the Sherman Act forbids only those trade restraints and monopolizations that are created, or attempted, by the acts of individuals or combinations of individuals or corporations.” (at 135)[...]and “that where a restraint upon trade or monopolization is the result of valid governmental action, as opposed to private action, no violation of the Act can be made out.”(at 136)

<sup>137</sup> *Ibid.*, 139.

<sup>138</sup> *United Mine Workers of America v. Pennington* 381 U.S. 657 (1965) 670.

<sup>139</sup> Federal Trade Commission, *Enforcement perspectives on the Noerr-Pennington Doctrine: An FTC staff report* (2006) 14; Philip E Areeda and Herbert J Hovenkamp, *Antitrust law: an analysis of antitrust principles and their application* (2<sup>nd</sup> edn, Aspen Law & Business, New York, 2002) ¶1203, 174.

<sup>140</sup> Federal Trade Commission (n 139)15.

to interfere directly with the business relationships of a competitor.”<sup>141</sup> The other noted exception to the Noerr-Pennington immunity is conduct satisfying the requirements of the Walker Process Doctrine.

### **6.1.3.2. The enforcement of section 5 of the FTC Act and the scope of the Noerr-Pennington Doctrine**

The scope of the Noerr-Pennington Doctrine is the yardstick for successful antitrust enforcement by the FTC in cases that concern potential anti-competitive conduct that does not directly stem from the investigated party, but from a governmental agency involved in the process. In the past, the FTC has filed administrative complaints twice: (1) *in the matter of Bristol-Myers Squibb*,<sup>142</sup> and (2) *in the matter of Union Oil Company of California*,<sup>143</sup> both dealing with anti-competitive effects of governmental actions caused by the submission of misleading information to the relevant public authorities. The FTC has successfully concluded these investigations by entering into consent agreements with the alleged infringers. After having analysed the FTC’s enforcement approach concerning the scope of the Noerr-Pennington Doctrine, it will be possible to apply it to the facts of the AstraZeneca judgment in a hypothetical FTC investigation in order to determine whether the European approach is indeed more restrictive than the US approach, as has been implied by AstraZeneca in its appeal.

#### **6.1.3.2.1. In the matter of Bristol-Myers Squibb with regard to BuSpar**

Apart from other types of conduct which are deemed to have anti-competitive effects,<sup>144</sup> the US pharmaceutical company Bristol-Myers Squibb (BMS) had acquired a patent that allegedly covered its blockbuster drug BuSpar which was due

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<sup>141</sup> *Eastern Railroad* (n 136) 144.

<sup>142</sup> Federal Trade Commission, *Administrative complaint in the matter of Bristol-Myers Squibb*. FTC file No.0110046. < <http://www.ftc.gov/enforcement/cases-proceedings/0110046/bristol-myers-squibb-company-matter>>.

<sup>143</sup> Federal Trade Commission, *Administrative complaint in the matter of Union Oil Company of California* Docket 9305 (4 March 2003) < <http://www.ftc.gov/enforcement/cases-proceedings/0110214/union-oil-company-california-matter>>

<sup>144</sup> i.e. pay for delay settlement entered into with Schein Pharmaceuticals, Inc. For the sake of the argument the focus of the analysis will only lie on conduct related to the Noerr-Pennington Doctrine.



to expire on 21 November 2000.<sup>145</sup> Anticipating significant profit loss after patent expiry because of the huge success of BuSpar, BMS filed patent applications with the USPTO in 1999 with the aim of covering a method for creating a slightly different version of the core active ingredient 'buspirone'.<sup>146</sup> After the rejection of this first patent application, BMS managed to receive a patent from the USPTO that solely covered the use of this slightly different version of buspirone instead of the method of creation.<sup>147</sup> This patent was submitted to the Food and Drug Administration (FDA) and subsequently listed in the Orange Book, even though the patent did not satisfy the statutory requirements for an Orange Book filing.<sup>148</sup> This is possible because the FDA is not examining the submitted patents. The FDA only has the ministerial role of listing the patents in the Orange Book and thus has to rely on the correctness of the information provided.<sup>149</sup> Following the Hatch Waxman Act,<sup>150</sup> every generic drug applicant has to notify the brand company whose drug the generic company attempts to receive a generic authorisation that it does not infringe any of the brand company's patents that are listed in the Orange Book and cover the drug in question. The brand company can bring a patent infringement action against the generic applicant within 45 days after the notification.<sup>151</sup> The filing of such a lawsuit automatically triggers a 30-month delay of the generic approval by the FDA, regardless of the merits of the case.<sup>152</sup> In doing so, BMS was able to artificially delay generic entry into the market and extended its monopoly for BuSpar.<sup>153</sup>

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<sup>145</sup> Federal Trade Commission, *Analysis to aid public comment: In the Matter of Bristol-Myers Squibb Company File Nos. 001 0221, 011 0046, and 021 0181* (2003) <http://www.ftc.gov/os/2003/03/bristolmyersanalysis.htm>; Federal Trade Commission (n 142) 37-45.

<sup>146</sup> In the year 2000 BuSpar sales were over \$ 600 Million in the US.

<sup>147</sup> Federal Trade Commission (n 145); Federal Trade Commission (n 142) 37-45.

<sup>148</sup> Federal Trade Commission (n 142) 47, 50.

<sup>149</sup> 68 Fed. Reg. 36676, 36683 (June 18, 2003).

<sup>150</sup> The Hatch Waxman Act is the common name for the Drug Price Competition and Patent Term Restoration Act 1984 whose aim was to encourage early generic entry into the pharmaceutical market by providing generic companies with the possibility of an abbreviated new drug application, in which they could largely rely on the long new drug application of the brand company.

<sup>151</sup> 21 U.S.C. §355 (j)(5)(B)(iii).

<sup>152</sup> 21 C.F.R. §314.107 (b)(3)(i)(A).

<sup>153</sup> Federal Trade Commission (n 142) 48.

BMS argued that its submission of patent information to the FDA for the purpose of filing it in the Orange Book was to be regarded as petitioning to the state and, thus, barred from antitrust scrutiny.<sup>154</sup> Opposing this argument, the FTC found that the conduct falls outside the scope of antitrust immunity. “Petitioning” within the meaning of the Noerr-Pennington Doctrine is not achieved by every governmental process that leads to a governmental action. The petition must be directed to the state with the aim of *obtaining* a governmental action, indicating a process of argumentation, discussion, and finally persuasion of the government to act according to the petition.<sup>155</sup> This is only possible, if the government agency has discretion over the decision. Without any discretion the agency’s act is of mere ministerial nature.<sup>156</sup> This argument was further underlined by the fact that the FDA has no possibility and thus no discretion to revoke its own filing of a patent in the Orange Book following the submission of the brand company.<sup>157</sup> Finally, it was held that the boundaries of Noerr-Pennington Doctrine have to be drawn by distinguishing between discretionary governmental actions and mere ministerial decisions.<sup>158</sup>

#### **6.1.3.2.2. In the matter of Union Oil Company of California**

In this case the FTC charged Union Oil for a violation of section 5 of the FTC Act, as Union Oil engaged in anti-competitive conduct by wrongfully obtaining monopoly power in the market for petrol sold in California.<sup>159</sup> Union Oil participated in this standard setting process that led to the formulation of low-carbon emission standards for so-called “summer line” fuel mandated for sale in California for a

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<sup>154</sup> *In re Buspirone Patent Litig./In re Buspirone Antitrust Litig.* 185 F. Supp. 2d 363 (S.D.N.Y. 2002).

<sup>155</sup> *Brief of the FTC as amicus curiae In re Buspirone Patent Litig./In re Buspirone Antitrust Litig.* 185 F. Supp. 2d 363 (S.D.N.Y. 2002) 8.

<sup>156</sup> *Ibid*, 9 also citing *Litton Systems v. American Tel. & Tel. Co.* 700 F. 2d 785 (2d Cir. 1983) filing of a new tariff to the Federal Communications Commission would not amount to “petitioning” to the State which would be protected by the doctrine due to the mechanical nature of the filing.

<sup>157</sup> 21 C.F.R. §314.53(f); 68 Fed. Reg. 36676, 36683 (June 18, 2003).

<sup>158</sup> *In re Buspirone Patent Litig./In re Buspirone Antitrust Litig.* (n 154) 369, 370.

<sup>159</sup> Federal Trade Commission (n 143).

period of up to eight months each year.<sup>160</sup> The set standard overlapped significantly with the patent portfolio of Union Oil because of the company's misrepresentation during the standard setting process and thus enabled Union Oil to acquire monopoly power. This conduct had a direct impact on competition and consumers due to the licensing agreements which the fuel refining industry had to enter into in order to be able to produce the "summer line" fuel. The arising costs for royalties of 5.75 cents per gallon were almost entirely passed on to the consumer.<sup>161</sup> *"But for Union Oil's fraud, [the standard setting body] would not have adopted regulations that substantially overlapped with Union Oil's concealed patent claims."*<sup>162</sup>

Union Oil asserted that its conduct was within the scope of antitrust immunity. It stated that the alleged conduct influenced the standard setting body in a quasi-legislative action instead of a quasi-adjudicative one and that only the latter would fall outside the scope of immunity and therefore result in antitrust liability.<sup>163</sup> However, stating that *"misrepresentations, condoned in the political arena, are not immunized when used in the adjudicatory process"*,<sup>164</sup> and that *"in less political arenas, unethical and deceptive practices can constitute abuses of administrative or judicial processes that may result in antitrust violations"*,<sup>165</sup> the FTC held that the appropriate distinction to grant antitrust immunity must be between the political and non-political arena, taking into consideration the context of the proceedings and the nature of the relevant communication<sup>166</sup> and not the distinction put forward by Union Oil.

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<sup>160</sup> Federal Trade Commission, 'FTC Charges Unocal with Anticompetitive Conduct Related to Reformulated Gasoline, Press Release' (04 March 2003) <<http://www.ftc.gov/opa/2003/03/unocal.shtml>>.

<sup>161</sup> Ibid.

<sup>162</sup> Federal Trade Commission (n 143) 80.

<sup>163</sup> Federal Trade Commission, *In the matter of Union Oil Company of California: Union Oil Company of California's Motion for Dismissal of the Complaint and Memorandum in Support Based Upon Immunity Under Noerr-Pennington* Docket 9305 (28 March 2003) <<http://www.ftc.gov/enforcement/cases-proceedings/0110214/union-oil-company-california-matter>>.

<sup>164</sup> *California Motor Transport Co. v. Trucking Unlimited* 404 U.S. 508 (1972) 513.

<sup>165</sup> *Allied Tube & Conduit Corp. v. Indian Head, Inc.* 486 U.S. 492 (1988) 499.

<sup>166</sup> Federal Trade Commission, *In the matter of Union Oil Company of California: Opinion of the Commission by Timothy J. Muris* Docket 9305 (7 July 2004) <<http://www.ftc.gov/enforcement/cases-proceedings/0110214/union-oil-company-california-matter> > 30.

Applying this distinction, the submission of misleading information is only protected by the Noerr-Pennington Doctrine when it takes place in the political arena. For the distinction between the political and non-political arena, the FTC has identified several factors: (1) the degree of governmental discretion, (2) the ability to determine causation should be taken into account, and (3) the extent of necessary reliance on the petitioner’s factual assertions. These factors can also be intertwined. The degree of discretion has a direct impact on accountability, the possibility of judicial review and ultimately on the scope of immunity. A misrepresentation is more likely to cause a certain governmental action if the governmental agency has no discretion regarding its decision. The lack of discretion is a strong indicator for the materiality of the misrepresentation to the governmental decision, as the decision would not have been made in the absence of the misrepresentation.<sup>167</sup> In the case of a political decision, it can be impossible to establish whether a given misrepresentation caused the government to act as it did, as it entails unfettered discretion.<sup>168</sup> The final factor of the necessary reliance on the factual assertions directly relates to the findings of the FTC in the case against BMS which has been discussed above. Only in areas where considerable discretion exist is it possible to assess given statements on their correctness. It is recognised that the political arena is based on contentious political opinions that are not necessarily based on true statements or might only contain the “partial truth”. However, political parties are aware of this fact and have the experience to balance these contending forces.<sup>169</sup> Agencies do not necessarily have this experience or might not even have any discretion<sup>170</sup> and thus they have to rely on the correctness of the facts provided to them.<sup>171</sup> This line of argumentation is again related to the FTC’s finding in the first case. The notion of the Noerr-Pennington

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<sup>167</sup> Areeda and Hovenkamp (n 139) ¶203, 186.

<sup>168</sup> Federal Trade Commission (n 166) 35.

<sup>169</sup> Areeda and Hovenkamp (n 139) ¶203, 175.

<sup>170</sup> See discussion of the ministerial role of the FDA in the case of Orange Book filings in section E2(a).

<sup>171</sup> Federal Trade Commission *supra* (n 166) 34, *Clipper Express v. Rocky Mountain Motor Tariff Bureau, Inc.* 690 F.2d 1240 (C.A.Cal. 1982) 1261 ‘the adjudicatory sphere is much different to the political sphere, in which the falsity of information could be revealed in debates, whereas in the adjudicatory sphere information must be reliable and thus accurate.’

Doctrine is to cover only petitions which try to persuade an agency to act in a certain way.

Finally, with regard to the nature of the relevant communication, the FTC states that a mere error that led to a decision in a non-political process is not sufficient for the conduct to fall outside the scope of Noerr-Pennington immunity. Without ‘knowing falsity’ there would be no abuse of a government process.<sup>172</sup> The FTC advocates that the misrepresentation or omission must firstly be deliberate, secondly subject to factual verification and thirdly central to the legitimacy of the affected governmental proceeding.<sup>173</sup> Thus any communication to the government or one of its agencies that is regarded as not being in the political arena and qualifies as misrepresentation is not protected by the antitrust immunity of the Noerr-Pennington Doctrine.

#### **6.1.4. Application of the FTC approach to AstraZeneca’s conduct**

This section finally undertakes the hypothetical exercise of scrutinising AstraZeneca’s conduct in Europe by applying the FTC’s approach to the submission of misleading information to patent offices following section 5 of the FTC Act. Doing so makes it possible to establish whether the European approach is indeed overly restrictive in comparison to the United States or whether the FTC would come to a similar conclusion as the EU courts.

In determining the hypothetical antitrust scrutiny following section 5 of the FTC Act it is necessary to establish the degree of discretion that the seven patent offices across Europe have had during the application procedure for the patent extensions by AstraZeneca. If the patent offices were to have had a mere ministerial role in granting the patent extension, AstraZeneca’s conduct would fall outside the scope of the Noerr-Pennington Doctrine following the Bristol-Myers Squibb test, meaning they could have been scrutinised by section 5 of the FTC Act. In case of limited discretion, the conduct could still be scrutinised by the FTC provided the requirements of the Union Oil test are satisfied.

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<sup>172</sup> Areeda and Hovenkamp (n 139) ¶203, 183.

<sup>173</sup> Federal Trade Commission (n 166) 36.

#### 6.1.4.1. Bristol-Myers Squibb test

As discussed above, this test distinguishes between discretionary governmental action and a mere ministerial action. The level of discretion of the patent offices which have received AstraZeneca's SPC applications must therefore be at issue. Such discretion refers to an at least partially subjective decision which is based on the judgment and the expertise of the relevant examiner at the patent office. This should not be the case if the examiner is adhering to rules and regulations, namely by simply applying the relevant provisions to the application at hand. Art. 3 of the SPC regulation<sup>174</sup> provides that a SPC *shall* be granted if, at the time of the application for such an extension, the product is still protected by a basic patent, a valid market authorisation for the drug exists, the product has not been subject to such an application before and that the market authorisation provided is the first market authorisation to place the product on the market in the European Union. The criteria that have to be fulfilled in an SPC application are of an objective nature, compared to general patent application criteria such as 'novelty' and 'non-obviousness' that might be subject to the personal judgement and expertise of the relevant patent examiner. If these objective criteria are met, the applicant is entitled to the patent extension. Were it to have been the intention of the legislator to give the patent offices the discretion to decide on these kinds of application, it would have phrased the provision differently by replacing 'shall grant a SPC' with 'may grant a SPC'. So it can be argued that the relevant patent offices had no discretion regarding the outcome of the SPC application but had to apply objective criteria to the facts of the case, which led to an entitlement to the patent extension, if these criteria were met. Although this conduct cannot be categorised as a mere "FDA style" ministerial role, given that the patent offices do not grant every application on receipt without scrutiny, this conduct should not be regarded as discretionary.

Indeed, certain procedural rules of the regulation might have been ambiguous or interpreted ambiguously by AstraZeneca's counsel during the

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<sup>174</sup> Council Regulation (EC) 469/2009 of the European parliament and the Council concerning the supplementary protection certificate for medicinal products, [2009] OJ L 152/1.

application procedure,<sup>175</sup> which led to different situations and outcomes in front of the patent offices. Some accepted the provided date of the effective market authorisation, whereas other patent offices considered this date to be false and regarded the technical market authorisation date as the correct one.<sup>176</sup> Such ambiguity should be resolved by means of statutory interpretation and should not lead to any type of discretion. Discretion gives the agency who exercises it the right to rely on its own judgment and expertise in the field. Applying the same rule in different cases could therefore lead to different outcomes. These differences are intentional, as it is often necessary to apply laws or rules flexibly to accommodate certain types of conduct on a case-by-case basis.<sup>177</sup> Ambiguity might also lead to different outcomes, but such an outcome is unintended and therefore warrants statutory interpretation. The aim of statutory interpretation is to decide which interpretation of an ambiguous rule is the correct one to be followed, thereby providing legal certainty.

Hence, the reactions of the patent offices should be characterised as a form of statutory interpretation and the differences between the outcomes of the application procedures in front of the different patent offices should not be mistaken as a form of “individualising discretion” of a general rule by the patent offices.<sup>178</sup> The different outcomes are rather an inevitable by-product of an administrative interpretation of law by several national agencies made necessary due to the lack of judicial interpretation on supranational level at the time. The legislative intention for the introduction of supplementary patent extensions at a European level has been the harmonisation of national legislation to further promote the single European market.<sup>179</sup> The argument can further be supported by

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<sup>175</sup> *AstraZeneca v European Commission* (n 2) 383. Instead of the actual date of the first market authorisation in the Union (technical market authorisation), AstraZeneca interpreted the correct date to be the effective first market authorisation, meaning the date of completion of all necessary administrative steps which are needed to launch the actual product.

<sup>176</sup> *AstraZeneca* (n 6) 150-153.

<sup>177</sup> Charles H Koch Jr. ‘Judicial review of administrative discretion’ (1985) 54 *George Washington Law Review* 469, 472.

<sup>178</sup> *Ibid*, 471 et seq.

<sup>179</sup> “A uniform solution at Community level should be provided for, thereby preventing the heterogeneous development of national laws leading to further disparities which would be likely to

the fact that the ambiguous question of the correct statutory interpretation of the term ‘market authorisation’, within the meaning of the SPC regulation, has ultimately been referred to the Court of Justice by means of a preliminary reference.<sup>180</sup> Following the preliminary reference, the Court ruled in favour of the technical market authorisation. It is therefore possible that the ambiguity of the SPC regulation at the time of AstraZeneca’s applications to the patent offices did not in fact lead to a discretionary decision by the offices. Indeed, each patent office applied objective criteria to the SPC applications which cannot be influenced by the applicant. Following the FTC’s distinction in the BMS test between a mere ministerial role and unfettered discretion, the centre of gravity of the agencies’ behaviour would now appear to lean towards the former rather than the latter, meaning it would not constitute a governmental action. AstraZeneca’s conduct would not be barred from a hypothetical antitrust investigation by the FTC, as the SPC would not be regarded as “obtained” by the patent offices within the meaning of the Bristol-Myers Squibb test.

#### **6.1.4.2. Union Oil test**

Even if one were to argue that AstraZeneca’s conduct does not fall within the scope of the Bristol-Myers Squibb test because of the patent offices’ ability to examine the applications and its right to reject applications that do not comply with the necessary requirements, AstraZeneca’s behaviour would nonetheless fall within the scope of the wider Union Oil test, leading to the same result. This conduct would not be regarded as petitioning to the state and would not be covered by the Noerr-Pennington Doctrine.

Referring to the Union Oil case, it must be determined whether the misrepresentation has caused the grant of the patent extension. This would be possible if the patent office has only “limited discretion” in the application process,

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create obstacles to the free movement of medicinal products within the Community and thus directly affect the functioning of the internal market.” Regulation (EC) 469/2009 (7).

<sup>180</sup> Case C-127/00 *Hässle* [2003] ECR I-14781. Referral by the German Federal Court of Justice following an appeal of a General Patent Court judgment regarding the validity of AstraZeneca’s patent extension in Germany.



which makes it necessary for the patent offices to rely on the presented facts. If this is the case, the application would not be regarded as petitioning within the scope of the Noerr-Pennington Doctrine. As seen above, the patent offices in question were able to examine the application at their own accord and request further information from the applicant. However, it is set out in the examination guidelines of several patent offices that the submitted date for the first valid market authorisation, which is necessary for the accurate calculation of the duration of the extension is not necessarily checked for its correctness. Checks are only made if there is reason to believe that the provided data is incorrect, which is largely due to the practical limitations of the patent offices who operate on limited resources.<sup>181</sup> Due to this very limited ability to verify the correctness of the provided date, a misrepresentation that is just aimed at this very factor is also likely to cause the relevant agency to grant a patent extension for a longer period of time or to grant an extension which the applicant would not be entitled to it at all. AstraZeneca's conduct before the patent offices in Germany, Finland, Denmark and Norway resulted in such an outcome.<sup>182</sup> To ultimately determine if AstraZeneca's conduct would fall outside the scope of Noerr-Pennington Doctrine, the nature of the communication would have to satisfy the misrepresentation requirements of the FTC. The European Commission has consistently stated:

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<sup>181</sup> Deutsches Patent- und Markenamt, *Richtlinien für das Prüfungsverfahren bei ergänzenden Schutzzertifikaten* <<http://www.deutsches-patentamt.de/docs/service/formulare/patent/p2799.pdf>> 6: "Zur Überprüfung dieses Erfordernisses fehlen die entsprechenden vollständigen Überprüfungs- und Recherchemöglichkeiten.[...]Des Weiteren wird im Rahmen der Wahrheitspflicht des Antragstellers davon ausgegangen, dass seine diesbezüglichen Angaben den Tatsachen entsprechen."; Österreichisches Patentamt, *Richtlinien für die Prüfung von Schutzzertifikatsanmeldungen* <[http://www.patentamt.at/Media/Richtlinien\\_Schutzzertifikat.pdf](http://www.patentamt.at/Media/Richtlinien_Schutzzertifikat.pdf)>, 15: 'Gemäß § 3 Abs. 1 SchZG 1996 erfolgt keine Prüfung darüber, ob die vorgelegte Genehmigung die erste Genehmigung für das Inverkehrbringen des Erzeugnisses in Österreich ist.'; Danish Patent and Trademark Office, *Order on Patents and Supplementary Protection Certificates* (2009) <[http://www.dkpto.org/media/183780/order\\_patents-spc.pdf](http://www.dkpto.org/media/183780/order_patents-spc.pdf)>, 24: "The [Danish] Patent Authority shall not verify whether the conditions in Article 3(d) of the Regulations are complied with."; Intellectual Property Office, *Supplementary Protection Certificates: Guide for Applicants* (2009) <<http://www.ipo.gov.uk/spctext.pdf>>, 16: "Unless there appears reason to do so, at present the examiner will not normally investigate whether the authorization specified was in fact the first authorization to place the product on the market in the UK as a medicinal or plant protection product."

<sup>182</sup> This differentiated outcome of patent extension application roots in a transitional provision in Council Regulation No 1768/92/EEC which entitled applicants in these countries only with an extension, if the first market authorisation was after 1 January 1988. In the case of AstraZeneca the correct date was 15 April 1987.

*“that the behaviour at issue does not consist of simple mistakes or isolated incidents of negligence, but is, on the contrary, characterised by continuity and consistency, indicating ‘subjective intent’ and full knowledge of the misleading character of the representations.”*<sup>183</sup>

AstraZeneca’s conduct has also been central to the legitimacy of the relevant patent office’s proceedings. Although not every patent office has granted a patent extension on the basis of the provided misleading information, AstraZeneca has succeeded in Germany, Austria, Finland and Norway. *But for* the submission of the misleading information, no patent extension would have been granted at all in the cases of Germany, Norway and Finland and only for a shorter period of time in the case of Austria.<sup>184</sup> AstraZeneca’s conduct therefore also fulfilled the misrepresentation requirements of the FTC.

As a result of this examination, it can be said, hypothetically, that the FTC would have been able to investigate AstraZeneca’s conduct for a potential infringement of section 5 of the FTC Act, engaging in acts that wilfully maintained its monopoly power. AstraZeneca’s misrepresentation would not have been covered by the antitrust immunity stemming from the Noerr-Pennington Doctrine. Ultimately, the European approach to AstraZeneca’s conduct is not overly restrictive compared to US antitrust enforcement by the FTC.

#### **6.1.5. Concluding remarks**

In the first instance, this section has shown that AstraZeneca’s line of argument regarding the overly restrictive approach of the General Court was indeed an ill-fated attempt to compare apples to oranges. The Walker Process Doctrine is not

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<sup>183</sup> *AstraZeneca v European Commission* (n 2) 338; also relying on AstraZeneca’s “ *Losec Post Patent Strategy*” which stated the intention to “*delay generic introduction through technical and legal hurdles because [e]very day of protected sales of Losec is worthwhile considering the huge sales volume projected at patent expiry and that [c]reating such barriers is a major priority.*” *AstraZeneca* (n 6) 271.

<sup>184</sup> *AstraZeneca v European Commission* (n 2) 592, 598.

comparable to the Court's judgment because of fundamentally differing enforcement policies in the US and in Europe.

The analysis of AstraZeneca's conduct in front of the different patent offices across Europe under the standard set out by the FTC in its enforcement of section 5 of the FTC Act has further shown that the FTC would be able to launch an investigation into AstraZeneca's conduct as such conduct would not be barred from antitrust scrutiny following the Noerr-Pennington Doctrine. AstraZeneca's criticism of the General Court's judgment is therefore not valid.

In more general terms, this section is advocating that caution is exercised when conducting comparative analyses of US and European antitrust policy issues. Similar cases do not necessarily warrant similar treatment – or in other words, the agencies come to a different result for good reasons even though the facts or prerequisites appear similar. Substantive as well as procedural standards should always be set while keeping the history and the underlying principles of the relevant policy in mind.

## **7. Conclusion**

On the one hand, the analysis has shown that the *AstraZeneca* judgment unfortunately fails to provide general guidance for the pharmaceutical business sector in relation to market definition. The application of the *AstraZeneca* market definition to a hypothetical market of antiepileptic drugs shows that the definition of the relevant market for Losec was highly fact-specific and should not be transposed to other markets. The General Court's fundamental assumption that doctors' prescribing inertia should be regarded as an exogenous factor to market definition is flawed. Not only has this assumption attracted criticism in the case of *AstraZeneca* itself, but the hypothetical analysis also provided evidence that doctors' prescribing inertia can be a key factor to consider when defining markets in an appropriate way, so that the market definition reflects the market realistically. A robust market definition is essential not only for Art. 102 investigations but also in relation to the applicability of block exemption regulations to investigations under

Art. 101 TFEU. Without a robust market definition the likelihood of Type I errors increases, especially in the pharmaceutical sector which is highly regulated and heavily reliant on intellectual property rights.

On the other hand, the detailed comparative legal analysis of AstraZeneca's claim that the European approach to the abuse of a dominant position by means of the submission of misleading information to patent offices is overly restrictive in comparison to the US approach and the Walker Process Doctrine has shown that the European Commission and the EU courts were right to dismiss this claim and opt for a European approach instead. The comparative analysis regarding the Walker Process Doctrine has demonstrated that, despite the similarity of the investigated conduct, the European Commission should not develop an approach based on requirements that are similar to the US doctrine. The underlying antitrust principles in the United States are simply too different to rely on the Walker Process Doctrine as a comparison benchmark.

This cautionary approach to comparative claims has important ramifications for analyses in subsequent chapters of this thesis, which discuss potentially anticompetitive types of conduct in the pharmaceutical industry that exist on both sides of the Atlantic. The fact that the pharmaceutical sector is highly regulated adds to the need to apply great care when undertaking comparative analysis. Even if the types of conduct were identical in the United States and Europe, their impact on the relevant sector could be very different due to the differences in the underlying regulatory regime.

The general conclusions that can be drawn from this initial comparative analysis of the *AstraZeneca* judgment as well as the careful approach to the comparative legal analysis itself should therefore act as a cornerstone and constant reminder for the comparative analyses to come. The next chapter examines the possible anticompetitive effects that could arise from pay for delay settlements and early entry agreements in the European context and develops a European theory of harm for both types of agreements that take regulatory differences between the European Union and the United States into consideration.

### III. A EUROPEAN THEORY OF HARM

#### 1. Introduction

Pay for delay settlements in the pharmaceutical sector are one of the hot topics in pharmaceutical antitrust at this moment in time. Originating from the United States, these settlements refer to a generic company agreeing with the brand company not to challenge the underlying patent to enter the market of the brand drug in return for a payment by the brand company. These kinds of settlements have been heavily scrutinised by the US antitrust authorities due to the significant anticompetitive potential, as they are foreclosing the market for generic companies and protect the brand company from patent challenges relating to the drug in question. Similar settlements have been identified by the European Commission in its pharmaceutical sector inquiry which was launched on 15 January 2008 and in its final report published on 8 July 2009.<sup>1</sup> At the same time, the pharmaceutical sector inquiry identified that the same parties also enter into so-called early entry agreements. In such a case, the generic company is allowed to enter the market of the brand drug while the brand drug is still patent protected. In return for this “early entry”, the generic company has to accept terms to such an agreement which includes the acceptance of the brand company’s control over the generic price, its exclusivity regarding the sourcing and distribution of the drug and, furthermore, its final decision on market allocation of the generic drug.

On the day of the final report’s publication, Commissioner Neelie Kroes stated that it was now clear what is wrong with the sector and that the time had come to act, insisting that the Commission would not hesitate to apply the antitrust rules to types of conduct that delay generic entry in an anticompetitive way.<sup>2</sup> The European Commission subsequently opened formal antitrust investigations against several pharmaceutical companies that had been subject to the sector inquiry for conduct that delayed generic entry and it also closely monitored every patent

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<sup>1</sup> European Commission, *Pharmaceutical Sector Inquiry: Final Report* (2009) <<http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/index.html>>.

<sup>2</sup> European Commission, *Antitrust: shortcomings in pharmaceutical sector require further action* (Brussels, 8 July 2009) <[http://europa.eu/rapid/press-release\\_IP-09-1098\\_en.htm](http://europa.eu/rapid/press-release_IP-09-1098_en.htm)>.

settlement that has been reached between a brand company and a generic company from 2009 to 2012.<sup>3</sup> Following these monitoring exercises of pay for delay settlements, the number as well as the volume of the settlements has been reduced substantially which was welcomed by the European Commission, as it regards these settlements as potentially anticompetitive.<sup>4</sup> In contrast, early entry agreements do not appear to be on the enforcement agenda of the European Commission, apart from having been identified in the pharmaceutical sector inquiry. The European Commission's actions after the sector inquiry, in addition to the strong statement intent by Neelie Kroes, suggests that the European Commission's enforcement priorities in the pharmaceutical sector are mainly on the scrutiny of pay for delay settlements – a type of conduct that has undoubtedly raised significant antitrust scrutiny in the United States and which led the US Federal Trade Commission to relentlessly warn of its anticompetitive potential in the United States. Yet the suggestion that pay for delay settlements in Europe should receive the same level of antitrust scrutiny as in the United States, due to their anticompetitive potential and effect in the United States should be rejected.

Following the rationale derived from the careful comparative legal analysis in the previous chapter one has to consider that, despite looking similar to the ones in the United States, pay for delay settlements in Europe do not necessarily have the same anticompetitive potential as in the United States. The same holds true for early entry agreements; they are not common in the US pharmaceutical industry, but this should not lead to the conclusion that they do not have any anticompetitive potential.

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<sup>3</sup> European Commission, *1st Report on the Monitoring of Patent Settlements (period: mid 2008 - end 2009)* (2010) <[http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/patent\\_settlements\\_report1.pdf](http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/patent_settlements_report1.pdf)>; European Commission, *2nd Report on the Monitoring of Patent Settlements (period: January-December 2010)* (2011) <[http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/patent\\_settlements\\_report2.pdf](http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/patent_settlements_report2.pdf)>; European Commission, *3rd Report on the Monitoring of Patent Settlements (period: January-December 2011)* (2012) <[http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/patent\\_settlements\\_report3\\_en.pdf](http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/patent_settlements_report3_en.pdf)>; European Commission, *4th Report on the Monitoring of Patent Settlements (period: January-December 2012)* (2013) <[http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/patent\\_settlements\\_report4\\_en.pdf](http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/patent_settlements_report4_en.pdf)>

<sup>4</sup> European Commission (n 3).

This chapter argues for a shift in the enforcement priorities of the European Commission away from a sole focus on pay for delay settlements towards a more diverse enforcement agenda that includes early entry agreements. Section 2 describes in detail the mechanisms behind pay for delay settlements, the incentives and benefits for the contracting parties in the United States and, most importantly, the differences in the European regulatory system. The section then proceeds to highlight the reduced anticompetitive potential of such settlements in Europe based on the rationale behind the antitrust enforcement in the United States. However, at the same time, a European theory of harm is proposed and developed, adapting the US rationale to the European framework and taking into consideration the fragmented nature of the European pharmaceutical sector.

Section 3 then turns to early entry agreements and their anticompetitive potential. First, details about the agreements, their content and their length are provided, before the main focus is placed on the potential anticompetitive foreclosure effect that an early generic entrant might have on subsequent generic entrants. The developed theory of harm is predominantly based on the significant first-mover advantage of the early entrant and the high inter-brand switching costs due to the peculiar structure of the pharmaceutical sector and the switching behaviour of stakeholders and consumers.

## **2. Pay for delay settlements**

Having originated in the United States, pay for delay settlements have only attracted the attention of the European Commission relatively recently. In the process of the pharmaceutical sector inquiry, the European Commission has identified patent settlement agreements that are similar to agreements known as “pay for delay settlements” which have been subject to longstanding scrutiny by the US Federal Trade Commission, US courts and various scholars.<sup>5</sup> These

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<sup>5</sup> Among many others Kevin D McDonald, ‘Patent Settlements and Payments that Flow the “Wrong” Way: The Early History of a Bad Idea’ (2002) 15 *Antitrust Health Care Chronicle* 2; Herbert J Hovenkamp, Mark D Janis and Mark A Lemley, ‘Anticompetitive Settlement of Intellectual Property Disputes’ [2003] 87 *Minnesota Law Review* 1719; Carl Shapiro, ‘Antitrust limits and patent settlements’ (2003) 34 *Rand Journal of Economics* 391; Marc G Schildkraut, ‘Patent-splitting

agreements are entered into by brand companies and generic companies following patent infringement litigation between the two parties. It is seen by the European Commission as one of the brand companies' 'employed instruments of the "tool box" to block and delay the entry of competing generic products on the market'.<sup>6</sup> If such settlements limit generic entry and include a value transfer from the brand company to the generic company then they should be regarded as potentially anticompetitive and, thus, a foul of competition law.<sup>7</sup> The European Commission has identified 207 settlement agreements within the period of January 2000 to June 2008. 99 out of the 207 settlements are deemed to impose limitations on generic entry and 45 of these include a value transfer from the brand company to the generic company which is regarded as a characteristic of pay for delay settlements.<sup>8</sup> These settlements included direct payments to the generic companies in excess of €200 million in total.<sup>9</sup>

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settlements and the reverse payment fallacy' (2003) 71 *Antitrust Law Journal* 1033; Thomas F Cotter, 'Antitrust Implications of Patent Settlements Involving Reverse Payments: Defending a Rebuttable Presumption of Illegality in Light of Some Recent Scholarship' (2003) 71 *Antitrust Law Journal* 1069; Thomas F Cotter, 'Refining the "Presumptive Illegality" Approach to Settlements of Patent Disputes Involving Reverse Payments: A Commentary on Hovenkamp, Janis & Lemley' (2003) 87 *Minnesota Law Review* 1789; Daniel Crane, 'Ease over accuracy in assessing patent settlements' (2004) 88 *Minnesota Law Review* 689; Anne-Marie C Yvon, 'Settlements between brand and generic pharmaceutical companies: A reasonable antitrust analysis of reverse payments' (2006) 75 *Fordham Law Review* 1883; C. S Hemphill, 'Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem' (2006) 81 *New York University Law Review* 1553; Mark W Murphy, 'Red flag or red herring? Reverse payments and the settlement of pharmaceutical patent litigation' (2008) 4 *European Competition Journal* 541; C. S Hemphill, 'An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition' [2009] 109 *Columbia Law Review*; Michael A Carrier, 'Unsettling drug patent settlements: A framework for presumptive illegality' (2009) 108 *Michigan Law Review* 37; Michael Kades, 'Whistling Past the Graveyard: The Problem with the Per Se Legality Treatment of Pay-for-Delay Settlements' (2009) 5 *Competition Policy International* 142; Michael A Carrier, 'Solving the Drug Settlement Problem: The Legislative Approach' (2009) 41 *Rutgers Law Journal* 83; Michael A Carrier, 'A Real-World Analysis of Pharmaceutical Settlements: The Missing Dimension of Product-Hopping' (2010) 62 *Florida Law Review* 1009; Aaron Edlin and others, 'Activating Actavis' (2013) 38 *Antitrust Health Care Chronicle* 16; Phillip E Areeda and Herbert Hovenkamp, *Antitrust law : an analysis of antitrust principles and their application* (2. ed. Aspen Law & Business, New York, NY 2013) ¶2046; Herbert J Hovenkamp, 'Anticompetitive Patent Settlements and the Supreme Court's Actavis Decision' (2014) 15 *Minnesota Journal of Law, Science and Technology* 3.

<sup>6</sup> European Commission (n 1) 466. (hereinafter it is referred to the relevant paragraph of the pharmaceutical sector inquiry)

<sup>7</sup> *ibid.* 1573.

<sup>8</sup> *ibid.* 746, 759, 762.

<sup>9</sup> *ibid.* 768.



The anticompetitive potential of these settlements in the United States is rather apparent following extensive discussion by US agencies, the courts and scholars. Before being able to establish their anticompetitive potential in the European context, it is necessary to identify the parties' incentives for entering into such settlements and the regulatory prerequisites that must be in place to achieve these incentives. This section therefore begins by explaining the mechanism behind pay for delay settlements and the theoretical economic incentives for both contracting parties. It then proceeds to describe how these incentives can be achieved in the context of the US regulatory system under the Hatch Waxman Act. Finally this section outlines the reasons why such conduct is not profitable under European pharmaceutical regulation (if one would only take the 'US factors' into consideration) and alludes to other factors like the competitive environment, which need to be taken into account in order to achieve market foreclosure under the European framework.

### **2.1. The mechanisms of pay for delay settlements**

Settlements are a means to end litigation in court and are generally regarded as favourable, as they are cost-saving and provide legal certainty.<sup>10</sup> This holds especially true for patent infringement litigation. The validity of patents is a highly complex area of law which typically requires a variety of expert evidence, which is why most countries employ specialist courts to determine the validity of the challenged patent. This makes patent infringement litigation a very lengthy and costly process. It can therefore be in every party's interest to end such litigation as quickly as possible.<sup>11</sup> The fundamental factor for the outcome of a settlement is the perceived strength of the parties' positions in the litigation and their likelihood of success. The pharmaceutical sector inquiry, however, brought to light the revelation that generic companies do not regard this factor as predominant. Their

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<sup>10</sup> Shapiro (n 5) 394.

<sup>11</sup> European Commission (n 1) 704.

major concern is actually the cost of litigation and the urge to avoid damages claims by the patent holder as these costs could be destructive for their business.<sup>12</sup>

Oddly, in the case of pay for delay settlements in the pharmaceutical sector, such a settlement takes place between the brand company and a generic company that intends to enter the market before the brand company's patent that covers the brand drug has expired. Entry or imminent entry usually leads to a patent infringement lawsuit of the brand company against the generic entrant. Such a lawsuit is a legitimate means by which the patent holder can defend its intellectual property rights. Patent settlements in general that end these litigation proceedings should have two possible outcomes, as they should mirror the likelihood of success in the litigation of the parties involved. Where a settlement is agreed, either: (1) the parties to the settlement regard the patent of the brand company as valid and therefore recognise the infringement of the generic entry prior to patent expiry, or (2) the parties regard the patent as invalid or not infringed, in which case the generic entrant should prevail. If the parties should agree to settle in both scenarios, it would be natural to expect in scenario (1) that the generic company would either refrain from entering the market before patent expiry or, alternatively, would agree to discontinue marketing the generic drug and most likely pay damages to the patent holder for the infringement of its intellectual proprietary rights. In scenario (2), the brand company would license the patent to the generic company enabling it to manufacture, market and sell the generic version on the market. Depending on the applicable cost rules, the brand company might also agree as part of the settlement to pay the generic company's legal costs or other costs that might have been incurred due to the lawsuit. Even a settlement in scenario (2) would be beneficial to the brand company as it only takes effect "inter partes", whereas the invalidation of the patent by court judgment would take effect "erga omnes" allowing every other generic company to use the chemical substance or the process which was protected by the patent in question.

In the case of pay for delay settlements specifically, aspects of each of these two scenarios can be observed, the generic company agrees not to enter the

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<sup>12</sup> Ibid. 721.

market until the patent has expired or even later than that. Under normal circumstances, “not entering the market” should indicate that the generic company has only a small probability of success in the anticipated outcome of the litigation. The litigated patent should be regarded as strong and valid. Additionally, one would expect a payment from the generic company to the brand company which might cover the brand company’s legal costs or possible damages. However, this is not the case in a pay for delay settlement. Contrary to the intuition set out in the two scenarios above, the brand company makes a payment to the generic company. This could be seen as a payment that is going in the wrong direction.<sup>13</sup> Effectively, the brand company pays the generic company for staying out of the market despite the fact that the generic company has accepted the validity of the brand company’s litigated patents in the same settlement agreement. In other words, the infringing party is being paid a considerable amount of money for staying out of the market – an outcome that the brand company should get for “free”. This can lead to the assumption that the exclusion of the generic company is not based on the strength of the patent, but simply on the amount of the payment which the companies agreed upon in the settlement.

In fact, pay for delay settlements create a “win-win” situation for the brand company and the generic company, which can be highlighted by discussing the economic incentives for both parties to enter into such a settlement.

## **2.2. Economic incentives of pay for delay settlements**

Initially, a patented drug enables the brand company that holds the patent(s) to reap monopoly profits for the period of patent protection. This changes following generic entry. The marginal cost of drug production is generally very low, whereas the research and development of drugs incurred by the brand company is very expensive. On the other hand, generic drugs only have to be bioequivalent, meaning that they have to be perfect substitutes by law.<sup>14</sup> Due to the fact that the

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<sup>13</sup> McDonald (n 5) 3.

<sup>14</sup> It has to be shown that the generic drug which is based on the same active ingredient as the branded drug has a rate and extent of absorption after the administration of the drug in the same

generic company can rely on the research and development of the brand company instead of having to invest in its own research and development of the drug, its production and marketing costs are minimal compared to the brand company, thereby enabling the generic company to sell the same drug at a significantly lower price. This is likely to result in a steep rise in market share for the generic company and significant profit losses for the brand company. It is therefore unsurprising that the brand company tries to delay such generic entry for as long as possible.

Pay for delay settlements are a tool used to accomplish such delay, as they are creating a “win-win” situation for the brand company and the first potential generic entrant. The brand company pays the generic company a lump sum for not entering the market. The generic company will only be willing to enter into such an agreement if this payment is adequately compensating for the lost profits, taking into consideration factors such as the likelihood of success and saved legal costs. The brand company has to at least reimburse the generic company the expected profits of sales, if not more; thereby effectively sharing its monopoly profits proportionately. Compared to actual generic entry, such a payment is still beneficial for the brand company. In the case of actual generic entry the brand company loses a significant percentage of its market share to the generic entrant within a short period of time, thus facing a high loss in profits.<sup>15</sup> The first generic entrant is gaining the market share, transforming the monopolistic market into a duopoly. However,

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molar dose that lies within predefined acceptable parameters. Satisfying these conditions shall ensure the similarity in terms of safety and efficacy. European Medicines Agency, *Guideline on the investigation of bioequivalence* (CPMP/EWP/QWP/1401/98 Rev. 1 2008) <[http://www.ema.europa.eu/docs/en\\_GB/document\\_library/Scientific\\_guideline/2009/09/WC500003011.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500003011.pdf)>

<sup>15</sup> Henry G Grabowski and John M Vernon, ‘Brand loyalty, entry and price competition in pharmaceuticals after the 1984 Drug Act’ (1992) 35 *Journal of Law and Economics* 331. ‘Generic prices fell to 78 percent of their initial value at the end of the first year and 65 percent at the end of the second year. This steep price decline together with the growing market share obtained by the generics is what causes overall market prices to decline’. Id at [336]; H. Grabowski and J. Vernon, ‘Longer patents for increased generic competition in the US. The Waxman-Hatch Act after one decade’ (1996) 2 *PharmacoEconomics* 110 ‘Drugs that have come off patent since 1991 experienced unit sales losses to generics of over 50% during the first several months of generic competition. Id at [121]; Ernst R Berndt and Murray L Aitken, ‘Brand Loyalty, Generic Entry and Price Competition in Pharmaceuticals in the Quarter Century after the 1984 Waxman-Hatch Legislation’ (2011) 18 *International Journal of the Economics of Business* 177 have found that this trend has even increased over the last decades leading to ‘much deeper and more rapid declines now than 15 years ago following initial implementation of the Waxman-Hatch legislation’ Id at [187].

its profit margins are considerably lower than those of the brand company. This makes the rapid increase in market share possible in the first place, but is also the reason for a comparatively low profit in relation to the market share. The brand company is therefore losing more profit than the generic company is able to gain, even though the combined market share stays the same. This profit loss, the extent to which might be unpredictable, can be limited and possibly controlled by the brand company when it enters into a settlement with the generic company. Additionally, the generic company is better off not entering the market and as a consequence customers cannot realise the potential gains of welfare which would have resulted from the competition between the two companies.<sup>16</sup>

### **2.3. Pay for delay settlements in the regulatory context**

So far this section has set out the theoretical mechanism of pay for delay settlements and has explained why the parties are willing to enter into such settlements. However, the degree to which this mechanism is implemented and the aforementioned incentives are realised by the parties is highly dependent on the regulatory framework in which the pay for delay settlements take place – the prime example being use of pay for delay settlements in light of the US regulatory framework surrounding the Hatch Waxman Act. The US regulatory regime could be regarded as the cradle for pay for delay settlements. This section therefore discusses such settlements in relation to the Hatch Waxman Act, before attention is turned to the evaluation of the anticompetitive potential of pay for delay settlements in the European context. Doing so enables one to draw comparisons between the European and US frameworks and, therefore, to highlight important differences that are likely to have a significant impact on the potential for anticompetitive effects.

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<sup>16</sup> C. S Hemphill and Mark A Lemley, 'Earning Exclusivity: Generic Drug Incentives and the Hatch-Waxman Act' (2011) 77 Antitrust Law Journal 947, 962.

### 2.3.1. The United States and the Hatch Waxman Act

As has been mentioned above, pay for delay settlements are in essence patent settlements that end ongoing patent infringement litigation. In the United States this patent infringement litigation between the brand company and the generic entrant is triggered by the generic company's drug approval application which it submitted to the FDA prior to the expiry of the brand company's patent.

According to the regulatory framework of the Hatch Waxman Act,<sup>17</sup> the generic applicant can apply to the FDA for drug approval prior to the expiry of the brand company's patents but must notify the brand company whose drug it wants to market as a generic version about the application. The so-called 'Paragraph IV certification' has to mention every related patent that was filed by the brand company in the FDA's Orange Book.<sup>18</sup> This gives the brand company the ability to challenge the generic application on grounds of patent infringement.<sup>19</sup> The requirement for the FDA to consider the listed patents in the Orange Book therefore creates a so-called patent linkage.<sup>20</sup> If the brand company decides to challenge the generic application, the FDA's decision on the generic approval is postponed by 30 months to enable the parties to resolve their patent dispute in court.<sup>21</sup> Following this postponement, the FDA approval of the generic drug will be effective from the date on which: (1) the patent expires, (2) the court reaches a decision on the non-infringement or patent invalidity in the patent litigation, or (3) the 30 months from the date of notification have expired,<sup>22</sup> whichever comes

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<sup>17</sup> The purpose of the Hatch Waxman Act is to incentivise generic companies to enter the market for a given drug prior to the brand company's patent expiry by challenging the validity of the brand company's patent. For a detailed description of the drug approval process for brand drugs and generic drugs in the United States please see Appendix sec. 1.

<sup>18</sup> The Orange Book is the FDA's register of all patents in relation to every brand drug that is registered with the FDA. For a detailed discussion see Appendix sec. 1.1.2.

<sup>19</sup> Hemphill and Lemley (n 16) 952.

<sup>20</sup> For a detailed discussion of the patent linkage see Appendix sec. 1.1.2.

<sup>21</sup> The intention behind the combination of the 30 months stay and the grant of generic exclusivity was to strike a just balance between the brand company's right to defend itself and its patents against unlawful infringement by a generic company that is seeking market entry prior to patent expiry and the need to incentivise the patent challenge by generic companies.

<sup>22</sup> Federal Trade Commission, *Generic drug entry prior to patent expiration: A FTC study* (2002) <<http://www.ftc.gov/reports/generic-drug-entry-prior-patent-expiration-ftc-study>> 41.

first.<sup>23</sup> Under normal circumstances, the court's judgment should have either declared the patent invalid, enabling generic applicants to enter the market because they no longer have to obey this patent, or declared that the patent had not been infringed by the generic applicant leading to the start a period of 180 days of generic exclusivity.<sup>24</sup> During this period of generic exclusivity, the FDA is not allowed to grant any further generic drug applications. After this period, as many generic companies as are willing to enter the market may do so simultaneously.

Pay for delay settlements are, however, able to skew these incentives in favour of the parties to the settlement and to the disadvantage of the final consumer. As mentioned above, the 30-month stay triggered by the FDA's approval decision of the generic application for market authorisation should allow the parties to litigate the patent infringement. Instead, the parties settle their patent infringement dispute. The generic company is nonetheless granted the 180 days of generic exclusivity, as the generic exclusivity is linked to the filing of the first generic drug approval application with the FDA and not to successful litigation.<sup>25</sup>

Because the initial patent infringement lawsuit has not been concluded by means of a judgment, but rather by means of settlement, the start of the 180 day exclusivity period is set to the date of actual generic entry, which has been stipulated by the parties in the settlement agreement. In doing so the parties can control and delay subsequent generic entry, as the FDA is not allowed to grant further generic drug approvals until the 180 generic exclusivity has elapsed. If the generic applicant agreed not to enter the market until 180 days prior to patent

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<sup>23</sup> Areeda and Hovenkamp (n 5) ¶12046c1.

<sup>24</sup> This exclusivity period was introduced by the Hatch Waxman Act with the intention to provide the first generic applicant with an incentive to incur the risk of patent infringement litigation and the costs that are associated with it. Elizabeth S Weiswasser and Scott D. Danzis 'The Hatch-Waxman Act: History, Structure, and Legacy' (2003) 71 *Antitrust Law Journal* 585, 603.

<sup>25</sup> Another possible misuse of the Orange Book requirements was the so-called "evergreening". Before the FDA changed its policy, which was confirmed by Congress in the Hatch Waxman Amendments in 2003, brand companies could file new patents in the Orange Book after the generic company had filed its Paragraph IV certification. This move required the generic company to file an additional Paragraph IV certification for the newly listed patent, which subsequently prompted a second 30-months stay. Hovenkamp, Janis and Lemley (n 5) 1754; In the case of PAXIL this mechanism was used to extend the stay-period in which the FDA was not allowed to grant any generic applications for PAXIL by 65 months. C. S Hemphill and Mark A Lemley, 'Earning exclusivity: Generic drug incentives and the Hatch Waxman Act' (2011) 77 *Antitrust Law Journal* 947, 967. Nowadays, the brand company is only entitled to one 30-months stay.

expiry,<sup>26</sup> the brand company's patent monopoly is effectively unchallengeable for the entire duration of the patent life, as the generic exclusivity functions as a regulatory bottleneck.<sup>27</sup> In return for this delayed entry of the first-filing generic company, the brand company typically compensates the generic applicant with a payment that is ideally larger than the estimated profits of the generic company.

Prior to 2003, subsequent generic entrants were unable to overcome this bottleneck and had no choice but to wait until the generic exclusivity had elapsed, as a brand company's patent could only be challenged by means of infringement. Compared to other sectors this fact is problematic in the pharmaceutical sector as a generic company cannot simply decide to enter the market with the aim of challenging a brand company through infringement. Entry requires market approval by the FDA. However, the FDA was not at liberty to accept any applications until the generic exclusivity of the first-filing generic company had elapsed.<sup>28</sup> This enabled the brand company - as patent holder - to withdraw itself from any possible patent challenge by entering into a pay for delay settlement.<sup>29</sup>

Having recognised this kind of regulatory bottleneck and the potential for the parties to a pay for delay settlement to foreclose the market up to a point that has been chosen by the parties, Congress amended the rules regarding the grant of the generic exclusivity in an attempt to mitigate this kind misuse of regulatory

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<sup>26</sup> Initially the parties to the settlement set the start date after the relevant patent had expired, thus exceeding the scope of the patent extending the pharmaceutical brand monopoly. However, this conduct has been found to be anticompetitive even by District Courts and the Court of Appeals for the Federal Circuit, which apply the "scope of the patent test." *In re Ciprofloxacin Hydrochloride Antitrust litigation* 544 F.3d 1323 (Fed. Cir. 2008), cert. denied, 129 S.Ct. 2828 (2009); *Valley Drug Co. v. Geneva Pharmaceuticals, Inc* 344 F.3d 1294, (11th Cir. 2003); *In re Tamoxifen Citrate Antitrust Litigation* 466 F.3d 187 (2nd Cir. 2005).

<sup>27</sup> Hemphill and Lemley (n 16) 963.

<sup>28</sup> *Ibid.* 963.

<sup>29</sup> In terms of patent law, this effect could be described as turning the rebuttable presumption of validity into effectively a non-rebuttable presumption, allowing the brand company to obtain a guaranteed legal patent monopoly. However, receiving a patent is not equivalent to an entitlement to exclude every competitor. The patent holder can only try to exclude its competitors and the probability of success is based on the strength of the patent itself. Shapiro (n 5) 395. Empirical evidence has shown that such a rebuttal of validity is not uncommon, especially in the pharmaceutical sector as the percentage of litigated valid patents is rather low. John R Allison and Mark A Lemley, 'Empirical evidence on the validity of litigated patents' (1998) 26 *AIPLA Quarterly Journal* 185. their dataset which includes 300 litigated patents of which 46% were actually invalidated by the courts. Federal Trade Commission (n 22) In the pharmaceutical sector this percentage is even higher. Between 1992 and 2002, 73% of the litigated patents have been invalidated.



procedures. The Medicare Act now limits the delay of the start-date of the 180 day generic exclusivity by the possible forfeiture of the generic exclusivity period.<sup>30</sup> This forfeiture forces the first generic applicant to start using its generic exclusivity or risk losing it, if a later-filing generic applicant wins its own patent lawsuit. However, the lawsuit has to be won in front of an appellate court.<sup>31</sup> If this is the case, the first generic applicant has to start using its generic exclusivity within 75 days.<sup>32</sup> An aggravating factor is that the later-filing generic applicant would have to be sued by the brand company in order to actually have the chance of winning the law suit. If the brand company refuses to do so, the later-filing generic applicant is still bottled up behind the first generic applicant that has been awarded with the generic exclusivity.<sup>33</sup> What the later-filing generic applicant can do is to file for a declaratory judgment against the generic applicant who was awarded generic exclusivity to use the 180 day exclusivity. However, according to Hemphill and Lemley,

*‘a declaratory judgment [...] is a chancy thing, because there is often dispute about whether the generic firm has standing to bring its suit.’<sup>34</sup>*

Even if the later-filing generic applicant is successful in either of the two possibilities above, the actual limitation of the delay is questionable. The generic company would have to file an ANDA application, win a patent lawsuit, win the appeal of this patent lawsuit, wait 75 days for the first-filing generic company to start using its generic exclusivity and then wait another 180 days until it can enter the market. This process can easily endure for several years and therefore can delay subsequent generic by a significant amount.

Ultimately, the start-date of the period of generic exclusivity is no longer set in stone by the settlement agreement between the brand company and the first generic applicant. That said, the above-described delay is still of such magnitude

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<sup>30</sup> *Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat 2066.*

<sup>31</sup> Carrier (n 5) 48.

<sup>32</sup> Ibid. 48.

<sup>33</sup> Hemphill and Lemley (n 16) 964.

<sup>34</sup> Ibid.

that it should not have a significant effect on the behaviour of the companies involved in pay for delay settlements and should not mitigate the significant anticompetitive potential that arises. Essentially, the brand company can still foreclose the market by paying off a single generic competitor.

The Federal Trade Commission has found that pay for delay settlements have a direct effect on the American consumer, who is either the final patient who has to pay the price for the brand drug privately or a possible co-payment depending on his healthcare plan, or the US government that is purchasing the drug for the Medicare programme or military hospitals. In a recent report, the Federal Trade Commission has estimated the cost and the period of delayed entry of generic entry that is caused by pay for delay settlements. According to this report, such settlements have delayed generic entry by an average of 17 months at a cost to the consumer of savings totalling US\$ 3.5 billion for the period of 2004 to 2009.<sup>35</sup>

In conclusion, a brand company can use a pay for delay settlement to foreclose the market itself until the generic exclusivity of the generic company that has entered into the agreement has expired. It can also ensure that its patents cannot be challenged by any potential competitor, thereby guaranteeing a legal monopoly – an outcome that might be within the technical boundaries of patent rights but which, at the same time, contradicts fundamental patent policy. This situation is exacerbated by the fact that the patent settlement itself is not based on the validity of the patent and the probability of success of getting the validity confirmed by a court's judgment. Rather, it is based on a payment by the brand company to the generic company which reflects, at least the estimated profit of the generic company if it were to have entered the market.

Having discussed the mechanisms of US pay for delay settlements by which generic entry can be delayed, the following section now addresses European pay

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<sup>35</sup> Federal Trade Commission, *Pay-for-Delay: How drug company pay-offs cost consumers billions*. A FTC staff study (2010) <<http://www.ftc.gov/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff>>.

for delay settlements and establishes in what way similar generic delay can be achieved.

### 2.3.2. Europe

In its pharmaceutical sector inquiry, the European Commission has identified a number of settlement agreements between brand companies and generic companies which are regarded as problematic and in need of closer scrutiny. The questionable characteristics of these settlements are their potential to limit generic entry to the market and the fact that they include a value transfer from the brand company to the generic company,<sup>36</sup> a situation similar to pay for delay settlements in the US. The question is whether these settlements also have a similar anticompetitive potential. In the US, the roots of the problem lie in the linkage of the approval for market authorisation with the economic consideration of patent protection as well as above-described effects of Hatch Waxman Act. With the settlement the brand company terminates its patent litigation against the generic company, including a value transfer in return for the preclusion of any possible patent challenge for the entirety of the patent life.

The European regulatory framework lacks most of the “US factors” that facilitate market foreclosure. Firstly, the European drug safety regulators that approve brand and generic drugs and grant market authorisations do not take economic factors, such as patent rights of the brand company, into consideration. Under EU law, such a patent linkage is not permitted.<sup>37</sup> Following European secondary legislation,<sup>38</sup> no other criteria apart from those regarding public health - such as the safety, the quality, and the efficacy of the relevant drug - should be taken into consideration when deciding upon the application for a market

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<sup>36</sup> European Commission (n 1) Box p. 269.

<sup>37</sup> *‘In the interest of public health, authorisation decisions under the centralised procedure should be taken on the basis of the objective scientific criteria of quality, safety and efficacy of the medicinal product concerned, to the exclusion of economic and other considerations.’*(emphasis added) Council Regulation (EC) No. 726/2004 of the European parliament and of the council laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (2004) OJ L 136 Recital 13.

<sup>38</sup> Ibid. Art. 81; Council Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use (2001) OJ L 311, Art. 126.

authorisation.<sup>39</sup> If it should be the case, that a market authorisation for a generic version of a drug interferes with the patent status of the originator drug, the issue should be resolved by means of private patent litigation in front of competent courts. The patent protection for a drug is an important issue for the pharmaceutical company, but separate from the safety and efficacy of the drug.

Secondly, the European regulation does not provide a framework similar to the Hatch Waxman Act. Similar to the US, the generic applicant does not have to pursue the same lengthy application procedure as the brand company but can rely on an abbreviated application procedure.<sup>40</sup> However, there is no difference between the first filing applicant and any subsequent generic company that decides to enter the market prior to patent expiry. Due to the missing patent linkage, the European framework has not created a bottleneck similar to the FDA. The relevant agency is not prevented from approving several generic drugs prior to patent expiry. Yet every generic entrant runs the same risk of being sued for patent infringement by the brand company which might occur separately to the approval process. For this reason, it is also not necessary to incentivise the first filing generic applicant with a period of generic exclusivity, as this applicant is not the only party that can challenge the validity of the brand company's patents that cover the drug in question. As a result the European drug approval regulation does not automatically create a type of temporary duopoly without potential for further entry within the market for a specific drug simply by granting the first market authorisation.

As a consequence, it is only possible for the brand company to secure duopoly profits for a certain period of time, in return for payment to the first generic entrant, if the number of possible generic entrants is very limited. For example, if only one of the potential generic entrants has the necessary financial power to take the risk of being sued for patent infringement, it would be a viable option to pay off this competitor.

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<sup>39</sup> European Commission (n 1) 336.

<sup>40</sup> Directive 2001/83/EC (n 40) Art. 10 (1).

However, if several potential competitors are equally strong or equally willing to take the risk of possible patent infringement litigation, the viable options for the brand company to achieve market foreclosure become more complex. If two generic companies intend to enter at the same time, the brand company would have to pay off both competitors instead of just the first. It has been suggested that paying off multiple entrants at the same time might even be cheaper than paying off just one competitor due to the price development of the drug in question after the market entry of multiple generic versions of the drug.<sup>41</sup> The entry of several generic companies will drive down the price of the drug faster and more significantly than just one entrant. Yet, if the overall output remains constant, the companies receive a smaller market share<sup>42</sup> and therefore expect smaller profits which, in turn, will have an impact on the amount of the payment which the brand company would have to pay for the company not to enter the market. For this to work, it is vital for the brand company to know which generic companies plan to enter the market. However, such knowledge is not necessarily given. Whereas in the United States a generic applicant is obliged to notify the brand company of its intention to enter the market, no such mandatory notification is required in the European framework due to the missing patent linkage.<sup>43</sup> Brand companies in Europe might anticipate generic entry by certain generic companies but only know for sure on the actual day of entry.

Furthermore, paying off all potential entrants at the same time would only be possible if the generic companies decided to enter simultaneously. However, generic companies in Europe may not only have an incentive to enter sequentially but also to delay entry themselves. If generic companies that are willing to enter the market are not planning to enter at the same time but rather sequentially without the brand company knowing about this, the brand company would have to

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<sup>41</sup> Kades (n 5) 158.

<sup>42</sup> Richard G Frank and David S Salkever, 'Generic Entry and the Pricing of Pharmaceuticals' (1997) 6 *Journal of Economics and Management Strategy* 89, found that following generic entry the market share shifts from the brand company to the generic company without finding a large increase in overall demand.

<sup>43</sup> The notification requirement in the US frame work is based on fact that the generic company has to notify the brand company that the generic company does not intend to infringe the brand company's patents or that it considers the patents as invalid.

enter into agreements with each of the generic entrants in turn. This could have a negative impact on the brand company's strategy to foreclose the market by paying off competitors.

As mentioned above, the incentive for the brand company is to retain its monopoly for a certain drug, despite sharing the profits with the first generic entrant who has agreed not to enter the market. A subsequent generic entrant is therefore still likely to have the same incentive to enter the market as the first generic entrant – to gain its share of the monopoly. Although the brand company is sharing part of its monopoly profit with the first generic entrant following the agreement, it is still the only company that is effectively selling the drug. The brand company would therefore have to pay off the second generic as well. If the second generic entrant is equally as strong as the first entrant who has already been paid off, the payment which is included in the agreement between the brand company and the second generic entrant is likely to be equal or higher than the first agreement, as the ultimate goal of full market foreclosure comes closer with every generic entrant that is being paid off. This game could theoretically be repeated “n” times, depending on the number of potential generic entrants to the market. In fact, the brand company should have to pay the highest price to the last potential entrant that can enter the market, as this pay-off would finally lead to the foreclosure of the market. The actual cost for the full foreclosure of the market would therefore depend on the number of generic entrants that are sequentially entering the market, with the cost per potential entrant rising with each pay-off. As a result, the brand company would incur significantly higher costs compared to those observed in the United States, if the aim is to fully foreclose the market.

In conclusion, it can be said that the incentives for brand companies to enter into pay for delay settlements with generic competitors in Europe must be different to the incentives in the United States. This is largely due to differences in the relevant regulatory framework. Brand companies in Europe cannot generally foreclose the market for a certain drug by paying off the first generic competitor. Furthermore, the brand company does not have exact knowledge about the intention of other potential generic entrant because of the lack of a mandatory

notification system, which makes the predictability of generic entry difficult. Although it might be efficient and cheaper to enter into agreements with all potential competitors at once, the scenario is only likely to be possible in a limited number of cases. Generic companies might rather have an incentive to conceal and delay their point of entry to reap a higher pay for delay from the brand company. Finally, it can be said that the European regulatory framework alone and the ensuing lack of achievability of the economic incentives of pay for delay settlements as described in the case of the United States, do not explain the reasons for why brand companies in Europe choose to enter into such agreements. Therefore the next section establishes factors that make pay for delay settlements in Europe a feasible strategy. After all, the European Commission has identified 45 pay for delay settlements in its pharmaceutical sector inquiry.

### **2.3.3. An alternative theory of harm for European pay for delay settlements**

Despite the lack of economic incentives for brand companies to enter into pay for delay settlements in Europe, these kinds of settlement have become increasingly more common in the EU. In its sector inquiry, the European Commission has identified 45 settlement agreements which are equivalent to US-style pay for delay settlements.<sup>44</sup> Assuming that brand companies as well as generic companies are driven by profit-maximising strategies and rational management decisions, the fact that the parties enter into pay for delay settlements should lead to the presumption that such agreements are economically beneficial. The relevant factors that make such settlements viable might simply be different compared to the United States.

The settlements identified by the European Commission mostly covered more than one Member State at a time. The highest number of such settlements was counted in Germany, the European Member State with the second highest pharmaceutical market value across all Member States. Surprisingly Austria, a Member State with a rather low market value, takes the second place whereas

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<sup>44</sup> European Commission (n 1) 762.

France, the Member State with the highest market value, is only midfield.<sup>45</sup> This unexpected outcome of the correlations between the number of settlements and the value of the market in the relevant geographic area suggests that the value of the pharmaceutical market is not the only - and maybe not even the primary factor - that is considered in the parties' decision about which Member States they enter into such a settlement agreement with.

The actual structure of the relevant pharmaceutical market could, for instance, prove an influential factor when deciding whether or not to enter into a pay for delay settlement, in addition to factors relating to market value and the national pharmaceutical regulations of the Member State in question. Despite the fact that the regulatory regime in the EU does technically not provide the possibility to foreclose the market by means of a single agreement, the actual structure of a pharmaceutical market in a given Member State might nonetheless facilitate such foreclosure. This could be the case, if the market lacks diversity in the generic sector. Although generic companies appear to be independent entities, they could in fact be a "generic branch" of the brand company or a subsidiary of a larger generic company.<sup>46</sup> Keeping this market consolidation in mind, an objectively diverse and competitive market - where there are a number of generic companies that have the potential to be future competitors in the after-market of a brand drug - could turn out to be a market with a lot less potential for competition due to the existence of a few pharmaceutical conglomerates that incorporate several generic companies or are at least majority shareholders of these companies. If this hypothesis holds true, it might be more feasible for the brand company to pay off all generic competitors that have actually the potential to enter the market, as their number would probably be a lot smaller compared to the number of generic

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<sup>45</sup> Ibid. 777.

<sup>46</sup> For example, the generic company Sandoz is the generic division of the brand company Novartis. Over the years, Sandoz itself has acquired a number of generic companies such as Lek Pharmaceuticals in 2002, Slovenia's largest pharmaceutical company, and HEXAL in 2005, one of Germany's biggest generic companies. Sandoz International GmbH, 'Sandoz History' <[http://www.sandoz.com/about\\_us/sandoz\\_history.shtml](http://www.sandoz.com/about_us/sandoz_history.shtml)>.



companies present at a national level.<sup>47</sup> Alternatively, it might also be the case that only a few generic companies are capable of entering “at their own risk” prior to patent expiry despite a large number of generic companies being present in the pharmaceutical sector as a whole. This might be the case in the European Commission’s proceedings against the French pharmaceutical company Servier and its recent decision against Lundbeck.<sup>48</sup> The Commission has sent a statement of objections to Servier and a number of generic companies taking the view that ‘patent settlement agreements between Servier and the generic companies were aimed at delaying or preventing the market entry of cheap generic versions of perindopril’.<sup>49</sup> In *Lundbeck* the European Commission has imposed a €146 Million fine on Lundbeck and a small number of generic companies because of the delay of generic entry of citalopram.<sup>50</sup>

#### 2.4. Concluding remarks

Compared to the US experience, the analysis has shown that pay for delay settlements in Europe are only likely to have a similar potential for anticompetitive foreclosure if the actual market structure is conducive to such foreclosure. If there are a large number of potential generic entrants, it is unlikely that the brand company will achieve foreclosure and equally unlikely that pursuing foreclosure will be profitable endeavour. However, these findings should not suggest that pay for delay settlements do not warrant antitrust scrutiny in Europe – after all, these settlements have become more common in Europe and the parties to the settlements would not enter into such arrangements if they were not profitable.

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<sup>47</sup> It would be ideal to test this hypothesis empirically, however that has been proved to be difficult. The European Commission’s dataset which was acquired in the light of the pharmaceutical sector inquiry would be ideal, as it covers requested information about settlement from brand companies as well as generic companies regarding 217 active ingredients, the main chemical entity of a number of identified so-called blockbuster drugs, across Member States. Unfortunately, the author has so far been denied access to this dataset.

<sup>48</sup> European Commission, *Antitrust: Commission fines Lundbeck and other pharma companies for delaying market entry of generic medicines* (Brussels, 19 June 2013) <[http://europa.eu/rapid/press-release\\_IP-13-563\\_en.htm](http://europa.eu/rapid/press-release_IP-13-563_en.htm)>.

<sup>49</sup> European Commission, *Antitrust: Commission sends Statement of Objections on perindopril to Servier and others* (Brussels, 30 July 2012) <[http://europa.eu/rapid/press-release\\_IP-12-835\\_en.htm](http://europa.eu/rapid/press-release_IP-12-835_en.htm)>.

<sup>50</sup> European Commission (n 48).

The focus of the antitrust scrutiny should be on the actual market structure, as it has been proposed by the alternative theory of harm.

### **3. Early entry agreements**

Having set out a potential theory of harm for pay for delay settlements in the European context in the previous section, attention now turns to early entry agreements in Europe and their anticompetitive potential based on a novel theory of harm. Following a descriptive discussion of the early entry agreements identified in the European Commission's sector inquiry, this section proceeds to set out the economic incentives for the two parties involved to enter into early entry agreements. Special focus is placed on the early generic entrant's first-mover advantage over subsequent independent generic entry. The discussion of the generic first-mover advantage is largely based on empirical evidence from across the globe dealing with the risk aversion and switching behaviour of prescribing doctors, pharmacists and patients. This discussion finally leads to an outline of the potential anticompetitive effects that might arise from this first-mover advantage in connection with the structure of the pharmaceutical sector. These factors are then used to develop a theory of harm.

In the course of its investigation into the pharmaceutical sector, the European Commission has identified 87 settlements between a brand company and a generic company which are regarded as early entry agreements.<sup>51</sup> In contrast to the above-mentioned pay for delay settlements, the brand company does not attempt to pay off the first generic entrant to stay outside the market, but rather "teams up" with the first generic entrant, even prior to the brand company's loss of patent exclusivity for the brand drug concerned. Having a generic version of the brand drug enter the market, even prior to patent expiry, should generally be seen as pro-competitive as it extends the monopolistic market to a duopoly. The creation of choice between the brand drugs and the generic one should have an impact on

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<sup>51</sup> European Commission (n 1) 808.

price. Additionally, there should not give rise to any concerns regarding quality given the strict drug approval regulations being in place and the necessity of bioequivalence between the brand drug and the generic.<sup>52</sup> Nonetheless, the European Commission has launched an investigation into these kinds of settlement during its sector inquiry, requesting detailed information about these settlements from the parties involved. Following the information provided, these settlements do not entail consistent provisions of the same legal nature. It is rather a combination of different agreements and it is exactly this combination from which the need for antitrust scrutiny arises.

Within the European Commission's findings, the majority of early entry agreements (63 out of 87) included a supply agreement, in which the brand company agreed to supply the generic company with the required quantity of the drug in order for it to be resold by the generic company. In most of these, cases these supply agreements provided the generic company with the obligation to purchase the quantities exclusively from the brand company, as opposed to producing the quantities itself.<sup>53</sup> For 45 of these 63 settlements, the supply price has been fixed by the parties for the entirety of the agreement or has been subject to renegotiations following material changes to the economic circumstances or following certain time periods.<sup>54</sup> The exclusivity of these agreements did not only cover the sourcing of the drug but also the geographic region in which the generic company is allowed to sell the drug. This restriction was achieved either by explicit clauses that prohibited sales outside the agreed territory or by means of a transfer of a market authorisation to the generic company restricted to the territory concerned.<sup>55</sup> In the scenario in which the market authorisation is restricted, the generic companies might still have the ability to apply for a market authorisation for other geographic areas, but are not assisted by the brand company in any way.

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<sup>52</sup> It has to be shown that the generic drug which is based on the same active ingredient than the branded drug has a rate and extent of absorption after the administration of the drug in the same molar dose that lies within predefined acceptable parameters. Satisfying these conditions shall ensure the similarity in terms of safety and efficacy. European Medicines Agency (n 14).

<sup>53</sup> European Commission (n 1) 843.

<sup>54</sup> *Ibid.* 822.

<sup>55</sup> *Ibid.* 849.

Thus, it is unlikely that such an application would be economically viable due to the incurred costs. Furthermore, 29 of the early entry agreements included a non-compete obligation for the generic company, which prevents the generic company from marketing alternative products manufactured by different brand companies if the alternative drugs contains the same active ingredient or is regarded as a competing product to the brand company.<sup>56</sup> A possibly aggravating factor concerning the agreements that include non-compete clauses is the fact that brand companies try to enter into these agreements with generic companies that not only have the relevant expertise, but are also able to capture significant market shares using their distribution systems and customer contacts.<sup>57</sup> If such generic companies enter into an agreement with the brand company, the possibilities for alternative products to enter the market might be limited as they would lack the usage of the superior distribution networks of the large generic companies.

The final key point that warrants antitrust scrutiny is the timing and the duration of early entry agreements. At least half of the identified agreements were entered into by the parties one year prior to the loss of exclusivity of the brand company's patent and, on average, the agreements exceeded the loss of exclusivity by two years,<sup>58</sup> however, in the most extreme case, it was more than 14 years.<sup>59</sup> This fact leads to a questionable situation where early entry agreements are in force for several years despite the fact that the bases on which they were concluded no longer exist. The brand companies were able to stipulate the clauses concerning market allocation, exclusive dealing, distribution and price determination only because of the potentially excluding power of their patents. Upon patent expiry, it could be argued that any agreement based on the relevant patent should lose its validity. Yet it should at least warrant close antitrust scrutiny due to the possible anticompetitive nature of the concluded clauses within the agreements.

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<sup>56</sup> Ibid. 847.

<sup>57</sup> Ibid. 838.

<sup>58</sup> Ibid. Box p. 310.

<sup>59</sup> Ibid. 853.

Generally speaking, it can be said that early entry agreements and the potential problems arising from them are faced two ways. On the one hand, allowing a generic company to enter the market prior to patent expiry should accelerate generic competition in the market and should thus be regarded as pro-competitive. On the other hand, early entry agreements consist of supply agreements with fixed prices, market allocation agreements and exclusive dealing agreements which exceed the patent life. Such a combination of factors should automatically raise suspicion of antitrust concern and, as such, demand scrutiny. Such agreements could have anticompetitive potential in the “post-patent market”, even if they do not exceed the patent life, by exploiting the pharmaceutical market structure and the inertia of the stakeholder in the market to switch from brand drugs to generics and between generics, thereby distorting the competitive process.

However, before we come to the discussion of the anticompetitive potential of early entry agreements, the economic incentives of the generic company as well as the brand company need to be examined.

### **3.1. Economic incentives for early entry agreements**

The parties to an early entry agreement only enter into such an agreement if it is economically sensible. Just as in the case of pay for delay settlements, the agreement must be more lucrative for the parties than litigating the patent infringement. This section therefore identifies the possible factors that influence the decision of the generic company to enter into an early entry agreement, before then proceeding to consider the incentives of the brand company.

#### **3.1.1. Incentives for the generic company**

Generic companies are likely to have a number of reasons for entering the concerned market by entering via an early entry agreement with the brand company, instead of trying to enter the market independently prior to patent expiry. For instance, the “agreed” entry prior to patent expiry eradicates the risk of

being sued for patent infringement by the brand company. An early entry agreement can also reduce the sunk cost that the generic company would incur during preparation for entry and, thus, would make the cost of entry and the anticipated revenues and profits more predictable. However, the predominant reason for entering into such an agreement with the brand company is most likely to be the first-mover advantage of the first generic entrant, which is the central argument in this discussion. This first-mover advantage is likely to be particularly significant in markets like the market for antiepileptic drugs, as described in the section on market definition in the previous chapter.<sup>60</sup>

#### **3.1.1.1. Incurred costs of production and marketing**

Before a generic company is allowed to market a generic version of a drug, it has to fulfil regulatory requirements just as the brand company did initially. Although the generic company does not have to undergo the very time-consuming procedure of clinical testing which is associated with the application of the brand company for the approval of a new drug including a novel active ingredient, the generic company must nonetheless file an abbreviated or abridged application with the relevant national medical regulator, proving the bioequivalence of the generic version in relation to the brand drug. Compared to the effort which the brand company has to undertake in order to receive approval, the generic approval has been designed to be significantly more time and cost-efficient. It is, however, still likely that the generic approval process takes up to 12 months to complete at a cost of several hundred thousand Euros.<sup>61</sup>

Additionally, the generic company has to set up a production line for the new generic drug. All these costs are sunk costs which have to be recouped by the generic company before making any profit.

Following an early entry agreement, the generic company does not necessarily produce the generic drug itself. In many cases, the brand company

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<sup>60</sup> See chapter II sec. 5.1.1.1. If patients are only switched once during their period of treatment to avoid the occurrence of epileptic seizures, it is essential for a generic entrant to be first.

<sup>61</sup> Susanne Keitel, *The Procedures to Apply for a Marketing Authorisation in the EU*, <[http://www.cpier.pku.edu.cn/doc/06EU/EU%20\(eng\).pdf](http://www.cpier.pku.edu.cn/doc/06EU/EU%20(eng).pdf)>

supplies the generic company with the finished product which is effectively the repackaged brand drug from the same production line.<sup>62</sup> Also, the generic company does not necessarily have to apply for the necessary market authorisation. As part of the early entry agreement, the brand company provides the generic company with a copy of its own market authorisation. The usual sunk costs can therefore be avoided by the generic company that is entering into an early entry agreement with the brand company. Of course this comes at the price of paying royalties to the brand company, but also avoids the risks associated with investing in a generic version of a brand drug without the security of financial return.

### 3.1.1.2. First-mover advantage

The major incentive for the generic company to enter into an early entry agreement is likely to be the first-mover advantage. In the pharmaceutical sector especially, the generic first-mover advantage can be significant in light of potential switching inertia.<sup>63</sup> Following a brief discussion of the general impact of switching costs on the first-mover advantage, this section focuses on the switching behaviour of (i) *prescribing doctors* and (ii) *dispensing pharmacists* separately and evaluates their impact on the switching costs of subsequent generic entrants, in order to highlight the significance for a generic entrant to consider the first-mover advantage.

Under an early entry agreement, the generic entrant will be the first generic company that sells its drug in the market. Such a first-mover advantage is usually extremely beneficial for the first generic entrant,<sup>64</sup> as - in theory - no further significant generic entry should be expected following the rationale behind

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<sup>62</sup> European Commission (n 1) 843.

<sup>63</sup> Doctors' prescribing inertia has already been addressed specifically in relation to antiepileptic drugs in Chapter II 5.1.1.1.

<sup>64</sup> In the United States, "most generic drug companies estimate that 60% to 80% of their potential profit for any one product is made during [180-day generic] exclusivity period [granted by the Hatch Waxman Act]." Daniel F Coughlin and A. D Rochelle, 'Hatch-Waxman Game-Playing from a Generic Manufacturer Perspective: From Ticlid® to Pravachol®, Apotex Has Difficulty Telling Who's on First' (2006) 25 *Biothechnology Law Report* 525, 525-26.

Bertrand competition.<sup>65</sup> By law, generic drugs have to be bioequivalent to the brand drug. In the case of the above-described terms of early entry agreements, the distributed generic drug might even be identical to the brand drug, as it is produced by the brand company and only repackaged and distributed by the generic company. So because the brand drug and the generic drug are homogeneous products by law, the pharmaceutical companies should not compete on quality but simply on price. Such price competition should lead to a reduction of the price down to marginal cost and should dis-incentivise any other generic entry into the market, as two companies are sufficient to drive down price in a given market.

Yet reality shows us that the first generic entrant might be safeguarded from further generic competition only until the patent protection of the brand company expires. By this point, multiple generic companies are entering the market.<sup>66</sup> This fact contradicts the general logic of Bertrand competition, which assumes that two pharmaceutical companies selling a homogeneous product in the market should be sufficient to drive price towards marginal cost. Thus, it needs to be assumed that generic drugs are differentiated products compared to brand drugs and not homogeneous, although generic drugs are required to be bioequivalent to the brand drug.<sup>67</sup>

Despite the fact that a given pharmaceutical market seems to be able to accommodate several differentiated generic versions of the same brand drug, the early generic entrant still has a significant first-mover advantage. One would expect an early generic entrant's market share to decrease with the entry of further generic competitors after patent expiry, as the generic drugs are likely to compete fiercely on price. Yet, as has already been shown in the previous chapter, the first

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<sup>65</sup> Under Bertrand competition two firms supply a homogenous good and only compete on price. Both firms have the same fix costs and have the same marginal costs. If firm 1 undercuts the price set by firm 2 it maximises its profits as it is supplying the whole market. The same is true for firm 2 in relation to firm 1. For both firms it is therefore sensible to set the price at marginal cost as it is not sensible to undercut this price. Ultimately, this situation therefore leads to allocative efficiency. Simon Bishop and Mike Walker, *The economics of EC competition law: Concepts, application and measurement* (University Sweet & Maxwell, London, 2010). 2-027, 2-028.

<sup>66</sup> The pharmaceutical sector inquiry has provided evidence that on average 4-5 generic companies enter the market within the first year after the loss of patent exclusivity. European Commission (n 1) 201.

<sup>67</sup> For the detailed discussion of bioequivalence see Chater II sec. 5.1.1.1.



generic entrant has a significant advantage over subsequent generic entrants in terms of market share.<sup>68</sup> Such an impact on the independent generic profits can affect the long-run equilibrium in the generic market.<sup>69</sup>

This significant impact on the first-mover advantage could be explained by the slow switching behaviour of consumers. The switching behaviour of consumers depends on the related switching costs in the relevant market. In pharmaceutical sectors across the world these costs are unusually high due to the unique structure of the sector. Such costs arise from the fact that the late entrant has to invest extra resources to persuade pharmacists and consumers to switch from the product of the first entrant to its own, in this case an identical product.<sup>70</sup> Switching costs can be influenced and increased by a number of factors, such as the consumer's imperfect information and uncertainty about the available choice in the market, as well as the quality of the product. These factors could have an impact on the perceived risk of switching of the consumer, and the possible brand loyalty towards the product of the first entrant. In the pharmaceutical sector, however, the perceived risk of the consumer is not the only thing at issue. Even more important is the perceived risk of the prescribing doctors and the dispensing pharmacists.

In ordinary markets, the second entrant to a market has to persuade the final consumer to purchase its products instead of the product of the first entrant. Yet, in the pharmaceutical sector for prescription drugs the patient as the final consumer is not the one making the decision on which product to purchase. The actual choice lies with the prescribing doctor who decides which drug is most appropriate to treat the patient's condition. Moreover, another player that has an impact on the actual distributed drug is the pharmacist. Particularly in the generic pharmaceutical market, the pharmacist might have the ability to substitute the prescribed drug with a cheaper generic drug.

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<sup>68</sup> Richard E Caves, Michael D Whinston and Mark A Hurwitz, 'Patent expiration, entry, and competition in the U.S. pharmaceutical industry' (1991) *Brookings Papers on Economic Activity* 1; Grabowski and Vernon (n 15); Aidan Hollis, 'The importance of being first: evidence from Canadian generic pharmaceuticals' (2002) 11 *Health Economics* 723. See chapter II sec. 5.1.1.1.

<sup>69</sup> David Reiffen and Michael R Ward, 'Branded Generics' as a Strategy to Limit Cannibalization of Pharmaceutical Markets' (2007) 28 *Managerial and Decision Economics* 251, 255.

<sup>70</sup> Marvin B Lieberman and David B Montgomery, 'First-mover advantages' (1988) 9 *Strategic Management Journal* 41.

By analysing empirical evidence, the remainder of this section therefore addresses the factors of imperfect information, perceived risk and brand loyalty. These factors have to be considered in relation to the decision making process of the prescribing doctor and the distribution process of the pharmacist, as well as the patient as the final customer. Although the patient cannot choose the drug himself, he is likely to be able to influence the decisions taken by the doctor and the pharmacist.

**(i) Prescribing doctors**

This section discusses the possible inertia of prescribing doctors to switch their patients from a brand drug to a generic drug. From a theoretical point of view, imperfect information about the availability and the uncertainty about the quality of a generic drug should not have a significant impact on prescribing doctors. Doctors should generally be aware of the different choices of drugs and they should not be concerned about the quality of generic drugs. By means of pharmaceutical approval regulations for generic drugs, the generic company has to prove to the relevant pharmaceutical regulatory body that a generic version is bioequivalent to the brand drug. The generic drug might not have the same colour or the same shape as the brand drug, but the generic drug has to be equally safe and efficient. In the chemical sense, the brand drug and its generic version must be identical. Having knowledge of this regulatory prerequisite, a doctor's prescription decision should be based predominantly on price. Generic drugs are known to be significantly cheaper compared to their brand counterparts. With further generic entry, the price for a generic drug should be driven down - faster and further.<sup>71</sup> It should be in the doctor's interest to prescribe the cheapest generic version of a drug as it reduces the price or the co-payment for the drug which the patient has to pay depending on the relevant pharmaceutical market's reimbursement scheme.

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<sup>71</sup> Berndt and Aitken (n 15) 187.

However, empirical evidence shows that doctors do not necessarily prescribe a new generic drug as soon as it enters the market, even if it is cheaper.<sup>72</sup> Doctors rather seem to wait a longer period before prescribing a generic drug, if they are uncertain about the generic drug's quality.<sup>73</sup> This finding implies that even doctors who are aware of the bioequivalence of generic drugs have a "learning experience" concerning the drugs' safety and efficiency.

This lack of trust by the doctors regarding the identical nature of generic drugs and the relevant brand drug, especially in the United States, might well have found its origins in a bribing scandal of FDA officials that occurred in 1989.<sup>74</sup> It has been shown by an interview study that this scandal has had a negative impact on the confidence of generic drugs.<sup>75</sup> Although Europe is short of such a scandal, the actual method that is used to measure bioequivalence for generic approval and the guidance set out by the European Medicines Agency (EMA)<sup>76</sup> arguably have an impact on a doctor's decision to delay prescribing a new drug until it has been tried and tested by other doctors. The EMA guideline states that bioequivalence is to be determined by statistical analysis using a group of healthy volunteers between the age of 18 and 55 and that the participants should be non-smokers, without a history of alcohol and drug abuse and should have a normal Body Mass Index.<sup>77</sup> This design of bioequivalence studies has been subject to criticism as a successful study only shows limited side effects and the equivalent effectiveness to the brand drug is not necessarily a good indicator for the effectiveness and safety of every

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<sup>72</sup> Jörgen Hellström and Niklas Rudholm, 'Uncertainty in the generic versus brand name prescription decision' (2010) 38 *Empirical Economics* 503. (using a panel data set of 17,821 prescriptions across 9 different substances in a Swedish county from 2001 to 2003, with mandatory generic substitution rules being introduced in October 2002. Pharmacists had to substitute unless the prescribing doctor expressly prohibited a substitution)

<sup>73</sup> *Ibid.* 518.

<sup>74</sup> Pola B Gupta, 'Survey of pharmacists: Impact of the generic drug scandal and implications for marketing generic drugs' (1996) 13 *Health Marketing Quarterly* 109, 112. Generic companies in the United States bribed FDA examiners and obtained market authorisations for their generic drugs which were based on false data. The submission of this data violated the good manufacturing practice, which ensures the safety, purity and effectiveness of generic drugs.

<sup>75</sup> *Ibid.* 117.

<sup>76</sup> European Medicines Agency (n 14).

<sup>77</sup> *Ibid.* 7.

patient.<sup>78</sup> The tested group consists of a selection of healthy average male and female subjects. This may not mirror society and the potential patients for a given drug. Patients do not necessarily have only a single medical condition and they are not necessarily in good physical shape, non-drinking and non-smoking. All of these variables could have a considerable effect on the absorption rate of a drug and therefore its effectiveness.<sup>79</sup> Prescribing doctors are therefore likely to delay switching to a new generic drug until evidence has shown that the generic drug does not cause adverse effects to their patients whose medical condition falls outside the characteristics of the tested group.<sup>80</sup>

Another factor that needs to be considered is the possible persistence of doctors in their prescription behaviour which might build a brand loyalty of the patients towards one specific product. Empirical evidence suggests that doctors are not indifferent across generic versions of a brand drug although they are bioequivalent.<sup>81</sup> Even in the absence of price differentiation, doctors show a preference for the generic version which their patients are accustomed to.<sup>82</sup> The longer a patient is being prescribed a certain generic drug the less likely it is that this patient will be switched to another generic drug by his doctor. The above-discussed risk aversion of doctors is likely to feed into this factor. The switch to a generic drug is delayed due the “learning process” of doctors. They only prescribe a generic drug if they are fully aware of all possible side effects and the drug’s effectiveness. The longer this process takes the less likely it is that a doctor switches a patient to a new generic drug because of the patient’s preference and possible brand loyalty.

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<sup>78</sup> Peter Meredith, ‘Bioequivalence and Other Unresolved Issues in Generic Drug Substitution’ (2003) 25 *Clinical Therapeutics* 2879.

<sup>79</sup> *Ibid.* 2879.

<sup>80</sup> Hellström and Rudholm (n 72). 518.

<sup>81</sup> Andrea Coscelli, ‘The importance of doctors’ and patients’ preferences in the prescription decision’ (2000) 48 *The Journal of Industrial Economics* 367. (using a patient-level data set of over 75000 observations in relation to prescription for anti-ulcer drugs by 350 doctors in Rome)

<sup>82</sup> *Ibid.* 363.

**(ii) Dispensing pharmacists**

Prescribing doctors are not the only players that have an impact on switching costs in the process of generic drug substitution. The doctor prescribes the relevant drug, but the patient receives the drug from the pharmacists. The pharmacist can therefore be seen as the middle man who is also likely to have an impact on the actual drug distribution. Most Member States have enabled the pharmacist to influence the drug distribution by affording them the ability to substitute a prescribed drug with a generic version of the brand drug or a different version of the generic drug itself.<sup>83</sup> So even if the doctor prescribes a brand drug, the pharmacist can or must substitute the prescription with a generic drug. In the Member States where generic substitution is not mandatory, the question has to be asked of how willing the pharmacist is to substitute a prescription, if the prescribing doctor has not done so due to the risk aversion and the above-described learning process. On the one hand, the pharmacist could act as a counterbalance to a risk-averse doctor and thus reduce the switching costs for the new generic entrant. This would be the case if the pharmacist would take the switching decision *for* the prescribing doctor who was unwilling to switch the patient. On the other hand, the pharmacist could also retain the level of switching costs. This would be the case if the pharmacist also showed a propensity towards risk aversion. The pharmacist might simply distribute the prescription of the risk-averse doctor, even though he might have the opportunity for substitution.

As is the case with the prescribing doctor, pharmacists are also aware of the bioequivalence of generic drugs compared to brand drugs, as well as other generic versions of the same brand drug. So in theory they should be indifferent to the generic version of the same brand drug. The predominant factor in their distribution decision should be price. However, the pharmacists' drug choice could also be influenced by their customers at the point of sale and it depends on the

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<sup>83</sup> 'Some Member States explicitly lay down this right for pharmacies in their legislation. In this case, pharmacists will make substitutions **if they are incentivised to do so** either by being able to make bigger margins or because of their regulated tariff structures. Others go further and make it **mandatory** for pharmacies to substitute. In such cases the pharmacies must dispense the cheapest version of the active substance available.' (emphasis added) European Commission (n 1) 367.

pharmacists' reaction to this kind of influence. Most patients/customers will probably not have realised the switch to a new drug at the "prescription stage" but, rather, at the pharmacy when exchanging the prescription for the actual drug. If such an influence is present at the point of sale, the preference and/or risk aversion of the customer would be closely related to the pharmacists' drug choice.

Empirical evidence has shown that customers/patients are not necessarily aware of generic drugs and the fact that generic drugs are bioequivalent to the brand drug.<sup>84</sup> According to an interview study, this lack of awareness causes confusion, if not suspicion and mistrust.<sup>85</sup> Customers were confused that they were being offered a different drug than the one they were being prescribed by their doctors and suspicious about the pharmacists' underlying motive to offer a different drug. They questioned the safety and efficacy of the drug and wanted to check this with their prescribing doctor.<sup>86</sup> This misconception of generic drugs and the role of the pharmacist have a direct effect on pharmacists' behaviour. According to the same evidence, pharmacists feel frustrated due to the lack of trust of their customers and the need to educate the customers about the efficacy and safety of generic drugs.<sup>87</sup> Due to these difficulties, some pharmacists mentioned that they do not even attempt to offer the customer other generic drugs instead of the ones the customer has previously been prescribed.<sup>88</sup>

This suggests that the behaviour of pharmacists can have a big impact on the substitution of generic drugs when they have discretion regarding the actual choice of drug depending on the prescription of the doctor, the generic availability and the national pharmaceutical regulatory scheme in place.

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<sup>84</sup> Reeta Heikkilä et al., 'Customers' and physicians' opinions of and experiences with generic substitution during the first year in Finland' (2007) 82 *Health Policy* 366, 373. (interview study based on questionnaires hand out to pharmacy customers who had rejected substitution (n=1243), customers who had accepted substitution (n=453) and interviews with prescribing doctors (n=49))

<sup>85</sup> Liz Gill and others, 'How do customers and pharmacists experience generic substitution?' (2010) 4 *International Journal of Pharmaceutical and Healthcare Marketing* 375, 386. (interview study conducted in Australia, Italy and Finland, using unstructured interviews to explore subjective experience of 15 pharmacists and 30 customers in relation to generic substitution. The interviewees provided similar responses across the three different countries.)

<sup>86</sup> *Ibid.* 386.

<sup>87</sup> *Ibid.*

<sup>88</sup> *Ibid.* 384.

In summary, it can be said that generic substitution on the pharmaceutical market is likely to be influenced by three different players – the prescribing doctors, the pharmacists and the patients/customers themselves. The behaviour of all three players is interdependent and cannot necessarily be separated. Doctors are reluctant to switch their patients to new generic drugs soon after the drugs have entered the market, due to risk aversion. The learning process that doctors undergo can be time-consuming. Yet the longer the process lasts the less likely it is that doctors will switch their patients to a new generic drug because of the patient's preference and habit.<sup>89</sup> The second potential opportunity for generic substitution is at the point of sale of the drug in the pharmacy. The pharmacist has the ability to amend the doctor's prescription and to sell a different generic version of the brand drug to the customer. This does, however, depend on the pharmacist's willingness to do so. This willingness is again influenced by worried customers who are not aware of the reasons behind generic substitution which can lead to mistrust against the pharmacist and resistance against new generic drugs. It is not suggested that generic substitution ceases to occur as soon as patients have developed a preference for a certain drug, but it is likely to take time to inform them about a newly available generic drug, its efficacy and safety. Such a delay in the actual distribution of a new generic drug to the customers can increase the switching costs significantly, raise the barriers to entry for future generic competition and ultimately, contributes to the generic first-mover advantage.

### **3.1.2. Incentives for the brand company**

After having discussed the incentives for the generic company to enter into an early entry agreement and in particular the generic first-mover advantage, the discussion now turns to the brand company's incentive. Compared to the generic company, the brand company ought to have incentives to enter into an early entry agreement which are of a different nature and of higher value.<sup>90</sup> By allowing a generic

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<sup>89</sup> Coscelli (n 81) 367.

<sup>90</sup> Following the generic entrant, the brand company loses more of its monopoly profits than the generic company can gain, which leads to consumer surplus. This has been one of the key arguments

company to enter early, the brand company waives its monopoly profits and agrees to transform a monopoly into a duopoly despite not having to do so due to patent protection of its brand drug. The predominant reason for this behaviour is likely to be the brand company's attempt to mitigate the dramatic loss of profits that is anticipated after patent expiry, which is discussed in the following section.

However, it is this attempt to mitigate the anticipated losses from generic entry, where one has to differentiate between, on the one hand, the brand company's business acumen to create new revenue on the "post-patent market" and, on the other hand, types of conduct that have the potential or are intentionally used by the brand company to distort the competitive process of the market and thus extend the brand company's profits in an anticompetitive way.

#### **3.1.2.1. Capturing generic profits**

A legitimate incentive for the brand company to enter into an early entry agreement based on its business acumen could be to capture generic profits. The brand company is likely to be able to extend its profits by agreeing to an early generic entrant. Undoubtedly, the brand company loses market share and revenue following the arrival of the generic entrant, but these losses are mitigated by the royalties that the generic company has to pay due to the early entry.

Indeed, losing market share and revenue close to the perceived patent expiry date can actually be beneficial for the brand company, as these factors are important determinants for the amount of generic entry. For example, the higher the hospital sales of a brand drug one year prior to patent expiry the larger the number of generic entrants.<sup>91</sup> The theory that the loss of market share and revenue is mitigated by the use of an authorised generic is given weight by an FTC study on authorised generics.<sup>92</sup> The interim findings have shown, using retail quantities as a

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for pay for delay settlements, discussed above in section 2.2. Because the brand company has more to lose, its incentives to enter into early entry agreements should theoretically be higher than for the generic company.

<sup>91</sup> Fiona M Scott Morton, 'Barriers to entry, brand advertising, and generic entry in the US pharmaceutical industry' (2000) 18 *International Journal of Industrial Organization* 1085, 1102.

<sup>92</sup> Authorized generics are generic versions of brand drugs that are marketed by the relevant brand company itself.



measure to show the impact of authorised generics on the market, that the combined quantities of the brand drug plus the authorised generic dispensed by the brand company is higher than the market share of the brand company alone, following subsequent generic entry. Although the market share of the brand drug initially decreases due to the authorised generic, the combined market share of the brand company after independent generic entry is higher in comparison to the brand company's market share without the authorised generic when faced by independent generic entry.<sup>93</sup> Using authorised generics in the United States is seen by the brand companies as a strategy to 'capture value after the brand drugs lose exclusivity without cannibalising the brand business.'<sup>94</sup>

This "recapturing effect" is another likely result of early entry agreements, despite the fact that authorised generics in the United States are largely marketed by brand companies themselves and, thus, do not result from an agreement between a brand company and a generic company. Parts of the generic profits are captured indirectly through the royalties which the generic company has to pay in return for the early entry.

However, concern for anticompetitive potential arises when the brand company is effectively able to control the early generic entrant, as shall be shown in the next two sections.

### **3.1.2.2. Control over the first generic entrant**

The biggest incentive for the brand company to enter into an early entry agreement with the first generic entrant is likely to be the brand company's effective control over the generic entrant. It has been established by the European Commission's sector inquiry that the early entry agreements impose a number of restrictions on the generic company. The majority of the agreements identified constitute supply agreements. The brand company agreed to supply the generic entrant with the

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<sup>93</sup> Federal Trade Commission, *Authorized Generics: An interim report* (2009) <<http://www.ftc.gov/reports/authorized-generics-interim-report-federal-trade-commission>> 16.

<sup>94</sup> Federal Trade Commission, *Authorized Generic Drugs: Short-Term Effects and Long-Term Impact* (2011) <<http://www.ftc.gov/reports/authorized-generic-drugs-short-term-effects-long-term-impact-report-federal-trade-commission>> 67.

drug.<sup>95</sup> These exclusive sourcing agreements were mostly combined with provisions relating to price setting and territorial restrictions. In some agreements, the price for supplied drugs was fixed at up to 90 per cent of the price charged to wholesalers.<sup>96</sup> Additionally, the generic companies were only allowed to re-sell the drug in a specific territory, stated in the agreement or as a condition of the market authorisation which the generic company was provided with by the brand company.<sup>97</sup> In doing so, the brand company can indirectly control the price as well as the quantity of the distributed drugs. One could say that the brand company is keeping its own “pet competitor”, as the generic company can only compete on the terms set out by the brand company in whose interest it is to keep the generic company on “a short leash”.

### **3.2. Anticompetitive potential of the “pet competitor”**

I argue that it is the creation of this kind of “pet competitor” which harbours the anticompetitive potential of early entry agreements.

As has been mentioned before, a number of the early entry agreements identified contain non-compete obligations.<sup>98</sup> These obligations not only prevent the generic company from competing with the brand company in certain geographical areas, but also prevent the generic company from marketing the generic drugs of other competing brand companies. The generic company is thus deprived of the opportunity to decide which drug from which brand company it wants to sell. This kind of “freedom of choice” has been repeatedly stressed by the EU courts to be an important factor in the finding of abuse as it suffices to constitute the requirements for showing an exclusionary effect.<sup>99</sup> This non-compete obligation not only restricts the generic company in its business acumen but can

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<sup>95</sup> European Commission (n 1) 843.

<sup>96</sup> Ibid. 823.

<sup>97</sup> Ibid. 849.

<sup>98</sup> Ibid. 827.

<sup>99</sup> Case C-95/04 P *British Airways plc v EC Commission* [2007] ECR I-2331. at [67] reciting the judgment in *Michelin I* where it was held that one has to consider whether the granting of certain discounts restricts or removes the buyer’s freedom of choice when determining whether a pricing practice is abusive. Case 322/81 *NV Nederlandsche Baden-Industrie Michelin v Commission* [1983] ECR 3461. at [85]. Pinar Akman, ‘The role of ‘freedom’ in EU competition law’ (2013) *Legal Studies* 1.

also act as a barrier to the generic entry of competing brands. Brand companies have stated during the pharmaceutical sector inquiry that they prefer to enter into early entry agreements with generic companies that have a large distribution network.<sup>100</sup> So if a generic company with a large distribution network is not allowed to market generic versions of other competing brand drugs, then this constellation is likely to distort the market and to raise barriers to entry. Regarding such exclusivity agreements, the General Court held in *Tomra* that such agreements,

*'are incompatible with the objective of undistorted competition within the [internal] market, because they are not based on an economic transaction which justifies this burden or benefit but are designed to remove or restrict the purchaser's freedom to choose his sources of supply and to deny producers access to the market.'*<sup>101</sup>

However, the "freedom of choice" of the generic party to the early entry agreement is only one side of the coin. On the other side, the brand company can strategically use the first-mover advantage of the generic company coupled with its large distribution network to significantly raise the barriers to entry for other brand competitors which could have an exclusionary effect, as these competing brand companies are prevented from dealing with this generic company due to the imposed non-compete obligation. This foreclosing effect could be exacerbated by rebate schemes offered by the generic company with the large distribution network that rewards pharmacies for purchasing all needed generic drugs across all therapeutic classes that are in the product range of the generic company.<sup>102</sup> Not only would the generic company supply a large number of pharmacies because of its distribution network, it would also incentivise the pharmacies to not buy their

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<sup>100</sup> European Commission (n 1) quoting a brand company's strategy document: "*Launch [product name] via an early entry agreement with main players in the distribution channel, thus preventing disproportionate discounting of non-original [API name] containing products.*" *Id.* at [825].

<sup>101</sup> Case T-155/06 *Tomra Systems ASA and Others v European Commission* [2010] ECR 00 at [209].

<sup>102</sup> i.e. TEVA's rebate scheme offers pharmacies the nett-price for all its products that are included in the scheme, if the pharmacy spends at least £2500 per months. Teva also offers additional discounts of 3% and 5% once the pharmacy reaches certain expenditure thresholds (£4500+ and £6000+ respectively). TEVA UK Limited, *TevaTwo*, <<http://tevascheme.tevauk.com/pharmacy/tevatwo>>.

supplies from other generic competitors.<sup>103</sup> So even if a competing brand company uses a different smaller generic company to distribute its competing drugs at the pharmacy level, the generic version might find it difficult to enter the market, as a large number of pharmacies decide to deal only with the large generic company to maximize the potential rebates.

Such non-compete obligations should not be justifiable by the exclusionary power of the patent on which the early entry agreement is based, as this exclusionary power should only cover conduct that is directly related to the brand drug itself. Yet, in this case, such a causal link would be missing. If the non-compete obligation in relation to third party brand drugs were to be covered, the exclusionary power of the patent would go beyond the patent's scope. The aim of patent protection should be to safeguard an adequate return of profits for the innovator and should increase the incentive to innovate, but it should not have an excluding effect on the innovations of other parties which are not covered by the same patent.<sup>104</sup>

In addition to raising barriers to entry for competing brand companies, an early entry agreement is also likely to create barriers to entry for subsequent independent generic companies. In the European pharmaceutical market, generic companies can gain market approval for their generic version of a brand drug prior to the expiry of the brand company's patent protection and enter the market "at risk" – the risk being sued for patent infringement by the brand company. A generic company is likely to take this risk, if the incentive of potential profits is big enough. But this incentive is drastically reduced by the early generic entry and the associated first-mover advantage. Without the prospect of considerable extra profits from entering "at risk" prior to patent expiry, subsequent generic entrants are likely to wait until the relevant patent has expired and entry has become "safe".

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<sup>103</sup> Such a rebate scheme in itself could potentially constitute an infringement of Art. 102 TFEU, depending on the nature of the rebates. The detailed discussion of the rebate scheme itself is however outside the scope of this article.

<sup>104</sup> According to Art. 69(1) of the European Patent Convention, *'the extent of the protection conferred by a European patent or a European patent application shall be determined by the claims.'* Although the breadth of the claim can be subject to interpretation (see Art.1 of the Protocol on the interpretation of Article 69 EPC) the protection of the patent cannot be extended to related patents that are owned by other proprietors.

This effect can be exacerbated by the brand company, if it signals to generic companies that it will aggressively defend its patents. Ultimately, this could lead to an outcome whereby the brand company can retain the entirety of the drug's patent protection and prevent further entry, regardless of the merits or the validity of the concerned patents, simply by significantly reducing the incentive for such additional entry.

The creation of a "pet competitor" could also distort the competitive process on the relevant market beyond the patent life. Normally, one would expect prices to drop very quickly once the patent has expired. However, the brand company can control the generic company beyond the patent life, if the early entry agreements is entered into within a period of time that exceed the period of patent protection.<sup>105</sup> Coupled with the aforementioned first-mover advantage of the first generic entrant and the potential foreclosing effect of early entry agreements, the brand company could be able to prevent or at least delay the expected price drop and extend the period of time during in which brand company controls the supra-competitive price for the first generic entrant.

### **3.3. Countering potential criticism of the theory of harm**

The proposed theory of harm in this chapter is fundamentally based on the first-mover advantage of the first generic entrant and a potential deterrence or delaying effect on the switching from one generic drug to another. Some might argue that for such delay in switching to be viable, the conduct would have to delay subsequent generic entry itself, which is empirically proven to not always be the case.<sup>106</sup>

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<sup>105</sup> Some of the identified early entry agreements in the pharmaceutical sector inquiry were entered into 2 years before patent expiry and lasted on average 3.5 years, thereby exceeding the patent life. See *supra* section 3.

<sup>106</sup> Silvia Appelt, 'Entry and Competition in the Pharmaceutical Market following Patent Expiry, Evidence from Macro and Micro Data' (2011) < <http://edoc.ub.uni-muenchen.de/13108/>> showing empirically that subsequent generic entry in Germany is not necessarily deterred or delayed.

However, immediate entry of subsequent generic companies should not be confused with actual switching between generic drugs and nor should it give any indication of the actual magnitude or impact of the subsequent entry.

*Firstly*, a potential lack of deterrence or delay despite the decreased financial incentives could be explained by the fact that the generic company's decision to enter the market is taken before the decision on early generic entry. Early entry agreements are usually entered into within the last year of patent protection. However, if generic companies have to decide to enter a specific market several years before patent expiry, they are likely to have already invested in the preparation of the entry. The preparation of entry involves a number of issues: (i) The patent documentation of the brand company informs the generic company of the composition of the molecule, but not necessarily the process of how to achieve this specific composition. Depending on the complexity on the molecule, this process of identifying the correct composition can be lengthy; (ii) Prior to the application for marketing authorisation, the generic company has to prove the bioequivalence of the generic drug by conducting human clinical trials, which is the most expensive requirement for the application process.<sup>107</sup> The application fee for the marketing authorisation itself exceeds €100,000 with the European Medicines Agency<sup>108</sup> or over £100,000 with the Medicines and Healthcare products Regulatory Agency (MHRA).<sup>109</sup> These requirements are not only costly, but are also lengthy in process and have to be achieved prior to entry. Assuming that the generic company would then decide not to enter because of the existing generic competition by the early generic entrant, it would mean that the costs incurred would be sunk and unrecoupable. So it might be viable for the generic company to enter the market despite the existing competition and the reduced anticipated revenue and market

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<sup>107</sup> Information obtained through a discussion with a Professor of the School of Pharmacy at the University of East Anglia.

<sup>108</sup> European Medicines Agency, 'Explanatory note on fees payable to the European Medicines Agency, EMA/283580/2011' (2011) <[http://www.ema.europa.eu/docs/en\\_GB/document\\_library/Other/2011/03/WC500104380.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Other/2011/03/WC500104380.pdf)> 5.

<sup>109</sup> Medicines and Healthcare products Regulatory Agency, 'Marketing authorisations' <<http://www.mhra.gov.uk/Howweregulate/Medicines/Licensingofmedicines/Marketingauthorisations/index.htm#l6>>.

share, simply to recoup the cost incurred. However, such entry is not necessarily evidence for added competitive pressure in the market.

*Secondly*, the entry of generic companies into the market after patent expiry should not be seen as ultimate proof that strategic entry deterrence does not occur or might not be viable. The scope of the actual entry might be limited. The brand drug does not only exist in a single version which is then sought to be substituted by a single generic version of the drug. The brand company rather markets a range of different dosages and different forms of the drug, referred to as drug 'presentation'. For example,

*'[t]he tranquilizer Haldol [...] is sold in 1/2, 1, 2, 5, 10, and 20 milligram tablets, as a concentrated liquid in bottles, and as a solution for intravenous use in vials, ampules, and disposable syringes.'*<sup>110</sup>

Thus, generic entry alone and the presence of generic companies in the market should not be seen as a decisive indicator for the level of competition in the market. Generic companies may only market some of the brand presentations and therefore, do not cover the entire market. Depending on the generic substitution laws applicable in the different Member States, the limited range of generic presentations could be used to limit actual drug substitution and ultimately to reduce competition. According to Ellison,

*'if a doctor has prescribed that a patient takes one 100mg tablet per day, then the pharmacist may be prevented from dispensing 50mg tablets and instructing the consumer to take two tablets per day.'*<sup>111</sup>

*Thirdly*, the subsequent generic entrant might exit the market early. If it holds true that subsequent generic companies enter the market despite the strong competition of the early entrant, due to the fact that the entry decision is taken

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<sup>110</sup> Glenn Ellison and Sara F Ellison, 'Strategic Entry Deterrence and the Behavior of Pharmaceutical Incumbents Prior to Patent Expiration' (2011) 3 American Economic Journal: Microeconomics 1, 16.

<sup>111</sup> Ibid. 16.

prior the early entry, the companies may decide to leave the market following the low revenues that are to be expected due to the reduced market share.<sup>112</sup> As such, the impact would not only be on the entry of subsequent generic companies but also on the period of market presence of these generic companies.

Following the discussion of the possible factors that could limit the magnitude of a generic entry, one can ultimately argue that the possible lack of delay of subsequent generic entry post patent expiry should not be used as an argument to negate the existence of a generic first-mover advantage. The important factor is not the generic entry itself, but rather the extent of such entry and its impact on the switching behaviour between generic drugs.

#### **4. Conclusion**

In light of the discussion of pay for delay settlements and early entry agreements in the European pharmaceutical sector, several conclusions can be drawn regarding the enforcement priorities of the European Commission. Pay for delay settlements that have attracted extensive antitrust scrutiny in the United States are less likely to have an equally anticompetitive potential in Europe. Nonetheless, they might have an anticompetitive effect based on the competitive market structure, the peculiarities of the European pharmaceutical sector, its regulation and the manifoldness of similar but slightly different national pharmaceutical regimes. Still, the vast experience of US antitrust authorities is only likely to have limited applicability in Europe and it is key to take the actual market structure into consideration.

In contrast to pay for delay settlements, early entry agreements did not give rise to significant antitrust scrutiny in the United States and to the extent they did, largely as a form of value transfer in pay for delay settlements. This should not lead

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<sup>112</sup> Hollis (n 68) 729 showing for Canada that the first generic entrant has a stable increase in market share in the first 4 years after entry at an average of 34 per cent, whereas the second entrant only has a 10 per cent increase in market share in the same period. It has also been predicted that the first generic entrant has on average, a 35 per cent higher market share than it would otherwise enjoy as a result of the early entry. *Id.* at 731.



to the conclusion that early entry agreements cannot have anticompetitive potential in Europe. Despite the similarity of conduct, the underlying regulatory regime in Europe is different and more complex than in the United States. If a brand company can foreclose the market by paying off a single generic entrant there is no need for early entry agreements. However, if a brand company cannot foreclose the market, the second best option could be to “team up” with one generic entrant to exploit the peculiarities of the markets, the risk aversion of the prescribing doctors, pharmacists and patients and the resulting delay or lack of switching between generic drugs. The anticompetitive potential warrants particular scrutiny given their pro-competitiveness in the short-run. A multinational corporation that is focussed on profit maximisation is unlikely to be willing to share profits with a competitor without any long-run incentive to do so. Thus the European Commission should broaden its enforcement agenda. Pay for delay settlements should not be removed from the Commission’s focus. Such settlements might still pose an anticompetitive threat in Europe, relying on different regulatory mechanisms than those observed in the United States. However, the Commission should also review early entry agreements, as they could represent the “weapon of choice” for pharmaceutical companies, if market foreclosure through a kind of value transfer to the generic entrant is not viable.

Based on the developed theories of harm the following two chapters examine pay for delay settlements and early entry agreements under EU competition law and will determine whether these types of agreements can be addressed by applying Art. 101 TFEU and Art. 102 TFEU.

## IV. PAY FOR DELAY SETTLEMENTS

### 1. Introduction

Pay for delay settlements are in essence patent settlements between a brand company and a generic company, in which the brand company makes a value transfer to the generic company for which the generic company in return agrees to exit the market or to abstain from entering the market in the first place. In the EU experience, most of these settlements have been reached to end on-going patent litigation, but some were concluded in out-of-court disputes or during patent opposition proceedings.<sup>1</sup> In its 2009 pharmaceutical sector inquiry, the European Commission established that 45 out of the 207 settlements investigated were restricting generic entry and, in addition, were based on a value transfer from the brand company to the generic company. The value transfers in the 45 pay for delay settlements took place in a number of different ways. In some cases, the value transfer consisted of a direct monetary payment to the generic company, whereas in other cases it consisted of a licence granted to the generic, a distribution agreement, or a so-called “side deal” which provides royalty-free licences to the generic company or enables the brand company to purchase generic stock at a fixed price.<sup>2</sup>

As these settlements are likely to constitute agreements between competitors, one would be inclined to scrutinise this concerted conduct under Art. 101 Treaty on the Functioning of the European Union (TFEU). However, one should also consider antitrust scrutiny under Art. 102 TFEU. Pay for delay settlements are based on a patent owned by the brand company. Such patent protection confers a temporary regulated monopoly upon the brand company. Although one would need to consider market definition before determining whether such a legal patent monopoly translates into a dominant position of the brand company it is possible to

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<sup>1</sup> European Commission, *Pharmaceutical Sector Inquiry: Final Report* (2009) <<http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/index.html>> para 740. (hereinafter it is referred to paragraphs)

<sup>2</sup> *Ibid.* 762-768.

assume that the conferred patent is likely to significantly contribute to the dominant position of the brand company. By deploying Art 102 TFEU, a competition authority would also be able to address unilateral conduct by the brand company that is facilitated by a pay for delay settlement with a potential generic competitor. In this situation, an Art. 102 analysis might also be of strategic advantage to the competition authority. It could possibly rely on assistance from the generic company in its investigation, as the generic company that is a party to the pay for delay settlement is not subject to the investigation itself. Indeed, the European Commission has opened formal proceedings in a number of cases against both brand companies and generic companies in relation to the delay of generics based on Art. 101 TFEU as well as Art. 102 TFEU.<sup>3</sup>

The chapter is therefore structured as follows. Section 2 addresses pay for delay settlements as agreements between competitors in the general remit of Art. 101 TFEU. From an additional point of view, section 3 then focuses on the broader unilateral conduct of the brand company, which is facilitated or at least made possible through the use of a pay for delay settlement. The discussion in section 3 is not therefore complementary to the section 2 analysis of pay for delay settlements under Art. 101 TFEU but, rather, investigates a different type of abuse that encompasses such settlements. For the purpose of section 3, the brand company is assumed to be in a dominant position.

## 2. Agreements between competitors

In June and December 2013, the European Commission handed down two decisions against two brand companies and a number of generic competitors with regards to the delay of entry for generic competition. Both investigations were based on Art. 101 TFEU.

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<sup>3</sup> European Commission, *Antitrust: Commission opens formal proceedings against Les Laboratoires Servier and a number of generic pharmaceutical companies* (Brussels, 8 July 2009) <[http://europa.eu/rapid/press-release\\_MEMO-09-322\\_en.htm?locale=en](http://europa.eu/rapid/press-release_MEMO-09-322_en.htm?locale=en)>; European Commission, *Antitrust: Commission opens formal proceedings against pharmaceutical company Lundbeck* (Brussels, 7 January 2010) <[http://europa.eu/rapid/press-release\\_IP-10-8\\_en.htm](http://europa.eu/rapid/press-release_IP-10-8_en.htm)>.

In its *Lundbeck* decision, the European Commission imposed for the first time a fine on a brand company, Lundbeck, and a number of generic companies for delaying the market entry of a cheaper generic version of citalopram, an antidepressant drug.<sup>4</sup> The total of the fine imposed was in excess of €152 million. Although it is clear from the press release that the conduct in question constituted a pay for delay settlement and was investigated under Art. 101 TFEU, the Commission has yet to provide any details regarding its analysis. In a second decision, the European Commission has imposed a fine of €16 million on Johnson & Johnson and Novartis for the delay of a generic pain-killer based on fentanyl.<sup>5</sup> In the case of *Lundbeck*, the parties have since appealed the decision to the General Court.<sup>6</sup> The scene is therefore set for a period of uncertainty as we await the publication of the European Commission's approach to pay for delay settlements and for the General Court to hand down its first judgment with regards to pay for delay settlements in the European context. The aim of this section is to bridge this temporary uncertainty by devising and discussing an approach that the European Commission should take or should have taken, depending on the actual analysis used in the European Commission's decisions.

As part of the analysis of pay for delay settlements under Art. 101 TFEU, this section establishes whether a European approach to pay for delay settlements can be based on the EU courts' existing case law relating to trademark delimitation agreements and no-challenge clauses. Due to the lack of legal guidance offered by previous judgments and decisions on pay for delay settlements, the analogous application of this alternative body of case law may assist in establishing a European approach to these settlements. The analysis that follows, however, shows that neither set of alternative case law is "fit for purpose" with regard to the

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<sup>4</sup> European Commission, *Antitrust: Commission fines Lundbeck and other pharma companies for delaying market entry of generic medicines* (Brussels, 19 June 2013) <[http://europa.eu/rapid/press-release\\_IP-13-563\\_en.htm](http://europa.eu/rapid/press-release_IP-13-563_en.htm)>.

<sup>5</sup> European Commission, *Antitrust: Commission fines Johnson & Johnson and Novartis € 16 million for delaying market entry of generic pain-killer fentanyl* (Brussels, 10 December 2013) <[http://europa.eu/rapid/press-release\\_IP-13-1233\\_en.htm](http://europa.eu/rapid/press-release_IP-13-1233_en.htm)>.

<sup>6</sup> Case T-460/13 *Ranbaxy Laboratories and Ranbaxy (UK) v Commission* [28 August 2013] OJ C 325/71; Case T-472/13 *H Lundbeck and Lundbeck v Commission* [28 August 2013] OJ C 325/76; Case T-470/13 *Merk v. Commission* [30 August 2013] OJ C 325/74; Case T-471/13 *Xellia Pharmaceuticals and Zoetis Products v Commission* [30 August 2013] OJ C 325/75.

assessment of pay for delay settlements under Art. 101 TFEU. This section therefore goes beyond the boundaries of the European case law relating to anticompetitive agreements between competitors and develops a novel test for an investigation of pay for delay settlements, which is inspired by the recent US Supreme Court judgment in *FTC v Actavis*.<sup>7</sup> Following a cautious analysis of the rationale behind the US Supreme Court's judgment – taking into consideration the regulatory differences between the US and Europe, which have been established in the previous chapter – a structured effects-based analysis is proposed. The exercise of analysing the *FTC v. Actavis* judgment and adapting it to the European framework is not only motivated by the fact that it is a judgment of the highest judicial authority in the United States regarding pay for delay settlements. Furthermore, Alexander Italianer, Director General for Competition in the European Commission, has made the following statement in relation to the *Lundbeck* decision during a conference at the Fordham Competition Law Institute in New York City.

*'Incidentally, to those of you who are familiar with the Supreme Court's Actavis opinion, the factors taken into consideration by the Commission will sound familiar. Indeed, the Supreme Court looked at the same factors, in particular the size of the payment including as compared to the expected profits of the generic producer, and the lack of any other convincing justification.'*<sup>8</sup>

It should thus not be too far-fetched to consider the rationale behind the US Supreme Court's judgment in *Actavis* for the analysis of pay for delay settlements in the European context.

This section is structured as follows. Section 2.1.1. discusses whether patent settlements are to be considered as agreements in general, before examination is then afforded to whether the EU courts' case law relating to trademark delimitation

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<sup>7</sup> *FTC v. Actavis* 133 S.Ct. 2223 (2013). In this judgment, the US Supreme Court ruled for the first time on pay for delay settlements and gave guidance to the lower courts. For a detailed discussion see *infra* sec. 2.1.2.2.1.

<sup>8</sup> Alexander Italianer, *Competitor agreements under EU competition law: 40th Annual Conference on International Antitrust Law and Policy, Fordham Competition Law Institute* (New York 2013) [http://ec.europa.eu/competition/speeches/index\\_speeches\\_by\\_the\\_dg.html](http://ec.europa.eu/competition/speeches/index_speeches_by_the_dg.html).

agreements and no-challenge clauses can be used as guidance for the analysis of pay for delay settlements under Art. 101 TFEU. Section 2.1.2. examines the possible prevention or distortion of competition through pay for delay settlements and rejects the notion that such settlements should be scrutinised as restrictions by object. The effects-based analysis then discusses and considers the US Supreme Court's judgment in *Actavis*, including the FTC's amicus curiae brief in *Effexor XR*, as possible sources of guidance. Following this discussion, a novel "structured effects-based" approach to pay for delay settlements is developed, which acknowledges the general need for patent settlements and, as such, is not considered to be over-inclusive.

## **2.1. Analysis of EU pay for delay settlements under Art. 101 TFEU**

The first part of this chapter scrutinises the pay for delay settlement between the brand company and the generic company under Art. 101 TFEU. It addresses the nature of the settlement as an agreement and questions whether the prevention or distortion of competition should be regarded as a restriction by *object* or by *effect*. It does not question whether the brand company and the generic company are separate economic entities and, thus, undertakings in the sense of Art. 101 TFEU – this fact is assumed.

### **2.1.1. Agreements within the scope of Art. 101 TFEU**

This section first sets out the definition of an agreement following the relevant case law. Having set out and established that a pay for delay settlement constitutes an agreement, the section then turns to the question of whether the EU courts' case law in relation to trademark delimitation agreements and no-challenge agreements could be used as guidance to address pay for delay settlements.

The definition of an agreement and the type of conduct that determines an agreement within the meaning of competition law has had to be established through case law, as no statutory definition has been provided. In *Bayer v*

*Commission*,<sup>9</sup> the General Court provided what is now regarded as the “classic definition” of what constitutes an agreement.<sup>10</sup> In summarising the relevant case law, the General Court stated that

*‘in order for there to be an agreement within the meaning of Article [101](1) of the Treaty it is sufficient that the undertakings in question should have expressed their joint intention to conduct themselves on the market in a specific way’.*<sup>11</sup>

The concept is therefore based on the concurrence of wills between the parties. Yet not every “concurrence of wills” between two-or-more undertakings constitutes an agreement in the sense of Art. 101 TFEU. It has to have the purpose to “tie down the future”.<sup>12</sup> The agreement has to bind the contracting parties to act or abstain from acting in a certain manner on the market in the future. Agreements lacking this “future component”, such as commercial spot transactions, typically fall outside the scope of Art. 101 TFEU.<sup>13</sup>

It was also held that the form in which the concurrence of wills is expressed is irrelevant and it need not have to constitute a valid and binding contract under national law,<sup>14</sup> as long as it constitutes the faithful expression of the parties’ intentions.<sup>15</sup> In a string of cases, the European Commission and the EU courts have

<sup>9</sup> Case T-41/96 *Bayer AG v Commission* [2000] ECR II-3383.

<sup>10</sup> Alison Jones and Brenda Sufrin, *EU competition law: Text, cases, and materials* (5<sup>th</sup> edn Oxford University Press, Oxford 2014) 150.

<sup>11</sup> Case T-41/96 *Bayer AG v Commission* [2000] ECR II-3383. para.67 relying on Case 41/69 *ACF Chemiefarma v Commission* [1970] ECR 661 para. 112; Joined Cases 209/78 to 215/78 and 218/78 *Van Landewyck and Others v Commission* [1980] ECR 3125 para. 86; Case T-7/89 *Hercules Chemicals v Commission* [1991] ECR II-1711 para. 256

<sup>12</sup> Okeoghene Odudu, *The boundaries of EC competition law: The scope of Article 81* (Oxford University Press, Oxford, 2006) 82.

<sup>13</sup> Eric Gippini-Fournier, *The Notion of Agreement in a Vertical Context: Pieces of a Sliding Puzzle* <http://ssrn.com/abstract=1892742>, 4.

<sup>14</sup> Case C-277/87 *Sandoz prodotti farmaceutici SpA v Commission of the European Communities* [1990] ECR I-45. In *Sandoz* the sending of invoices to customer bearing the words “export prohibited” on the back was regarded as a tacit agreement. It was held that the export ban formed an integral part of the continuous contractual relationship between Sandoz and its distributors. Due to the continuous nature of this relationship, the distributors’ lack of protest against this restriction and the repeated orders despite the export ban were found to be the tacit acquiescence of the agreement.

<sup>15</sup> Case T-41/96 *Bayer AG v Commission* [2000] ECR II-3383, 69.

found “apparently unilateral conduct” which amounts to an agreement within the meaning of Art. 101 TFEU.<sup>16</sup>

However, in the case of a pay for delay settlement, identifying a concurrence of wills between the two parties should be straightforward. Under these settlements, the brand company and the generic entrant agree that the generic company will not enter the market for a pre-determined period of time, which is stipulated in the settlement in exchange for a value transfer, ie a lump sum of money. Such a settlement clearly constitutes an agreement which binds the contracting parties to act in a stipulated way in the future.

Nonetheless, the parties could argue that the settlement should not be regarded as an agreement in the sense of Art. 101 TFEU, but rather as a judicial order which led to the definite disposal of a legal dispute in front of a court. The European Court of Justice, however, has rejected this line of argument. It found that a settlement, despite being a judicial act that disposes of a legal dispute, must comply with substantive law principles applicable to every contract.<sup>17</sup> In *Bayer v Sülhöffer*, the European Court of Justice found again that with regard to the

*‘prohibition of certain ‘agreements’ between undertakings, Article [101(1)] makes no distinction between agreements whose purpose is to put an end to litigation and those concluded with other aims in mind.’<sup>18</sup>*

According to the settled case law, pay for delay settlements should therefore be regarded as agreements in the sense of Art. 101 TFEU and are not shielded from antitrust scrutiny as they might also constitute judicial acts.

Having therefore established that pay for delay settlements constitute agreements within the scope of Art. 101 TFEU, the discussion now turns to the

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<sup>16</sup> The conduct largely consisted of the systemic sending of invoices, orders or pricelists which included sales conditions imposed by the seller which were accepted by the buyers through acquiescence. E.g. Joined Cases 25 and 26/84 *Ford Werke AG and Ford of Europe Inc. v Commission of the European Communities* [1985] ECR 2725; Case 107/82 *AEG-Telefunken v. Commission* [1983] ECR 3151; Joined Cases 32/78, 36/78 to 82/78 *BMW Belgium v Commission* [1979] ECR 2435.

<sup>17</sup> Case C-258/78 *Nungesser KG and Kurt Eisele v. Commission (Maize Seed)*, [1982] ECR 2015, 84.

<sup>18</sup> Case C- 65/86 *Bayer AG and Maschinenfabrik Hennecke GmbH v. Heinz Sülhöffer*, [1988] ECR 5249, paras 14-15.



trademark delimitation agreements and no-challenge agreements in order to establish the possibility of extracting potential guidance for the scrutiny of pay for delay settlements under Art. 101 TFEU.

#### **2.1.1.1. Trademark delimitation agreements**

According to Marc van der Woude,<sup>19</sup> one possible approach could be to adopt an analogous application of the ECJ's case law on trademark delimitation agreements. These agreements are entered into in order to settle disputes which are caused by confusingly similar trademarks. Just as in the case of patent settlements, such agreements may be allowed in order to end time-consuming and expensive intellectual property litigation.<sup>20</sup> However, they are not immune to the application of Art. 101 TFEU and have attracted antitrust scrutiny in the past where they concerned parties from different Member States, as such settlements have to potential to amount to market allocation agreements, which would again be contrary to the European Union's common market imperative.<sup>21</sup> Although these settlements concern a different intellectual property right, they nonetheless deal with the possible antitrust scrutiny of otherwise permissible settlements. The discussion of the relevant case law could therefore be insightful for the European approach to pay for delay settlements. The approach to this kind of settlement was developed by the European Commission and the Court of Justice of the European Union over the course of several investigations.<sup>22</sup>

The case of *Sirdar/Phildar* concerned a trademark dispute between a French supplier and a UK supplier of knitting yarn. The two parties agreed not to use their respective trademarks in the opposing party's country. Apart from the UK and

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<sup>19</sup> Marc Van der Woude has been a judge at the General Court since 2010 and is the president of the 7<sup>th</sup> Chamber. Although the article discussing the possible application of trademark delimitation agreements and no-challenge clauses precedes his election in 2010, his comments are a good starting point in order to develop a European approach to pay for delay settlements.

<sup>20</sup> European Commission (n 1) para 707.

<sup>21</sup> Mark van der Woude, 'Patent Settlements and Reverse Payments Under EU Law' (2009) 5 Competition Policy International 182, 187.

<sup>22</sup> *Toltecs/Dorcet (IV/C-30.128)* Commission Decision 82/897/EEC [1982] OJ 1982 L 379/19; Case C-35/83 *BAT Cigaretten-Fabriken GmbH v Commission of the European Communities* [1985] ECR 363; *Sirdar-Phildar (IV/27.879)* Commission Decision 75/297/EEC [1975] OJ L 125/27; *Penneys (IV/29.246)* Commission Decision 78/193/EEC [1978] OJ L 60/19.

France, the two trademarks coexisted across the European Union. This very fact led the European Commission to find that the agreement constituted a market allocation agreement which had the object of restricting competition in the European Union.<sup>23</sup> In the case of *Penney's*, the European Commission found that the trademark delimitation agreement represented a restriction of competition but did not amount to an appreciable restriction. It was again stated that such an agreement could be contrary to Art. 101(1) if it constituted the means of a market sharing agreement. However, in the current case the parties could have prevented each other from using their respective trademarks by applying national trademark law.<sup>24</sup> It was therefore found that the parties had sought the “least restrictive solution possible”.<sup>25</sup>

In its *Toltecs/Dorcet* decision, the European Commission again applied the “least restrictive alternative test”. The case concerned two trademarks for tobacco products in Germany. Dorcet had been successfully registered by BAT Cigaretten-Fabriken GmbH as a trademark in Germany. Despite the fact that the trademark “Dorcet” had never been used in Germany, BAT opposed the application to register the trademark of “Toltecs” by Dutch company Segers. The dispute was resolved by way of a delimitation agreement in which BAT agreed to withdraw its opposition to Segers’ application but, at the same time, prohibited Segers from using the trademark Toltecs without BAT’s approval in Germany. Segers also agreed not to challenge the validity of BAT’s German registration for Dorcet.

The European Commission found in its decision that the delimitation agreement infringed Art. 101(1) TFEU as the parties did not adopt the least restrictive alternative with regard to the use of the trademark in question across the common market. Furthermore, the no-challenge clause prohibiting Segers from challenging a trademark that was not in use for more than five years, also

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<sup>23</sup> *Sirdar-Phildar* (n 22) 29.

<sup>24</sup> *Penneys* (n 22) 24, 25.

<sup>25</sup> *Ibid.* 25. The parties “*must seek the least restrictive solution possible, such as incorporating distinguishing marks, shapes or colours to differentiate the products of the two enterprises which bear identical or confusingly similar marks. A contractual obligation for the parties to assign or waive their trademark and trade name rights which would make it necessary for them to re-establish goodwill under other names may, under certain circumstances, have restrictive effects.*”

amounted to a violation of Art. 101(1).<sup>26</sup> In order to be able to determine the least restrictive alternative to avoid confusion between two trademarks, the European Commission had to make its own assessment of the trademark dispute. It held that the

*'Commission cannot find any serious risk of confusion between the word mark Dorcet and the word/device mark Toltecs. There is still no serious risk of visual or phonetic confusion if the pictorial component registered and used by Mr Segers (a wooden shovel lying across four tobacco leaves depicted within a distinctively-shaped gold ground) is disregarded, and the words Dorcet and Toltecs are compared. BAT's assertion that the marks sound similar and are therefore likely to be confused does not change this finding.'*<sup>27</sup>

In the case at hand, the Commission not only made its own assessment of the trademark dispute but also directly opposed German trademark law, as the delimitation agreement reflected national trademark law.<sup>28</sup> Thus it is unsurprising that BAT appealed the decision to the Court of Justice.<sup>29</sup>

Despite acknowledging that trademark delimitation agreements are *'lawful and useful if they serve to delimit, in the mutual interests of the parties, the spheres within which their respective trademarks may be used, and are intended to avoid confusion or conflict between them'*,<sup>30</sup> the Court of Justice stated that such agreements can be subject to antitrust scrutiny by the competition authority if the agreement in question also has the aim of dividing the market. *'The Community system of competition does not allow the improper use of rights under any national trade mark law in order to frustrate the Community's law on cartels'*.<sup>31</sup> This suggests that the European Commission has the authority to scrutinise trademark agreements even if they comply with national trademark law and, in doing so, the

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<sup>26</sup> *Toltecs/Dorcet* (n 22) 20, 21.

<sup>27</sup> *Toltecs/Dorcet* (n 22) 25.

<sup>28</sup> *Ibid.* 21.

<sup>29</sup> Case C-35/83 *BAT Cigaretten-Fabriken GmbH v Commission of the European Communities* (n 22).

<sup>30</sup> *Ibid.* para 33.

<sup>31</sup> *Ibid.*

Commission can make its own assessment of the risk of confusion and the dispute itself, bearing in mind that this is only the case if the agreement does not concern a genuine dispute.<sup>32</sup>

If one would apply this “least restrictive alternative test” by analogy to the situation of pay for delay settlements, the alternative would have to be measured against the outcome of the actual patent litigation. If the patent owner were to fully succeed in defending his patent, generic competition would not occur until patent expiry. So any settlement that would result in less restrictive effects compared to the judgment on the merits would not infringe Art. 101 TFEU.<sup>33</sup> The strength of the relevant patent would be at the core of the European Commission’s investigation and, should the Commission’s decision be appealed, at the core of the decision by the Court of Justice of the European Union. The Commission and the Court would therefore have to undertake their own assessments regarding the strength of the patent at issue and, ultimately, second-guess the decision of a specialist court, assuming that the parties have fought to the end of trial instead of settling the dispute. Following the decisional practice of the European Commission and the judicial precedent regarding trademark delimitation agreements, such an approach could be broadly envisioned. Yet the question remains whether such an approach would also be desirable.

The former Head of the Pharma Task Force of the European Commission, Dominik Schnichels, has repeatedly stated that it is not the intention of the European Commission Directorate General for Competition to second-guess the patent courts or doubt their judgments.<sup>34</sup> This position is understandable. Despite the fact that trademarks and patents are both classed as intellectual property rights, the level of assessment that was undertaken by the European Commission and the Court of Justice in the case of trademarks is rather different – and arguably straightforward – in comparison to the hypothetical assessment of a patent which

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<sup>32</sup> van der Woude (n 21) 188.

<sup>33</sup> Ibid. 194.

<sup>34</sup> Dominik Schnichels, *Keynote Address: GCR Conference "Settlement Agreements and Patent Abuse in the Pharmaceutical Sector 2010"* (Brussels 2010).

would need to take place in the case of pay for delay settlements. In its previous trademark assessments, the European Commission has had to decide whether actual labels or product names were too similar in terms of their appearance or sound and therefore likely to cause confusion for customers.<sup>35</sup> In contrast, the assessment of a highly technical patent, especially in the pharmaceutical sector, seems not only more difficult but impossible to achieve without expert advice.<sup>36</sup> The evaluation of a patent's validity in the pharmaceutical sector often involves the consideration of pharmacological and pharmaceutical properties as well as a comparison of the chemical structure of other compounds which have the maximum level of resemblance<sup>37</sup> and leads to divergent findings by specialist patent courts across Europe and in the United States.<sup>38</sup>

In light of these considerations, it does not seem appropriate for the European Commission to analogously apply the "less restrictive alternative test" to the case of patent settlements in the pharmaceutical sector.

#### **2.1.1.2. No-challenge clauses**

Pay for delay settlements could also be addressed by drawing from the ECJ's case law regarding no-challenge clauses. These clauses are contractual provisions that prevent the licensee in a licensing agreement from challenging the validity of the underlying intellectual property right.<sup>39</sup> Thus, they are likely to be an integral part of pay for delay settlements. So pay for delay settlements could possibly be addressed with the following case law, if the case law regards no-challenge clauses as being within the scope of Art. 101 TFEU.

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<sup>35</sup> Commission Decision of 15 December 1982 (*IV/C-30.128 - Toltecs/Dorcet*) (n 22) 25 *the pictorial component [...] a wooden shovel lying across four tobacco leaves depicted within a distinctively-shaped gold ground [...]and the words Dorcet and Toltecs [were] compared.*

<sup>36</sup> The assessment would have to determine whether the patent at issue can be regarded as novelty, constitutes an inventive step and can be used in industrial application. At the core of the determination of the "inventive step" criterion lies the question whether it can be differentiated from prior art. European Commission (n 1) 262-264.

<sup>37</sup> Israel Agranat and Silvy R Wainschtein, 'The strategy of enantiomer patents of drugs' [2010] 15 *Drug Discovery Today* <http://www.sciencedirect.com/science/article/pii/S1359644610000310>.167.

<sup>38</sup> *ibid.* 169.

<sup>39</sup> Jones and Sufrin (n 10) 904.

Originally, no-challenge clauses were considered in relation to contractual provisions in licensing agreements rather than patent settlements and it is fair to say that the European Commission, as well as the ECJ, was rather hostile towards them. In *AOIP/Beyrard*, Mr Beyrard, a self-employed inventor, granted AOIP an exclusive patent licence to manufacture and market certain types of rheostats which were used in various types of electric motors, control and switching devices. This licence included, amongst other clauses, a no-challenge clause regarding Beyrard's patents. In its decision, the European Commission found a no-challenge clause to be contrary to the public interest – the interest being the revocation of patents which should not have been granted in the first place.<sup>40</sup> In the case of *Windsurfing*, the Court of Justice shared the European Commission's sceptical view of no-challenge clauses. The Court held that such a clause '*constitutes an unlawful restriction of competition between competitors*'.<sup>41</sup> Licences that prevent patent challenges clearly do not fall

*'within the specific subject matter of the patent, [...] as it is in the public interest to eliminate any obstacle to economic activity which may arise where a patent was granted in error'*.<sup>42</sup>

In 1988, the Court of Justice had its first opportunity to discuss no-challenge clauses in relation to patent settlements. In *Bayer v Söllhöfer*, the parties cross-licensed patents held for construction panels and Bayer also agreed not to challenge the validity of Söllhöfer's patents.<sup>43</sup> Having reached the Court of Justice by means of preliminary reference from the German Federal Court of Justice, the European Commission offered a more liberal opinion towards no-challenge clauses, compared to the previously discussed case law. It argued that such a clause should not fall within the scope of Art. 101 TFEU, if the agreement has the purpose

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<sup>40</sup> *AOIP/Beyrard (IV/26.949)* Commission Decision 76/29/EEC [1976] OJ L6, 12.

<sup>41</sup> Case 193/83 *Windsurfing International Inc v Commission* [1986] ECR 611 para. 93.

<sup>42</sup> *Ibid.* para. 92.

<sup>43</sup> Case 65/86 *Bayer AG v Maschinenfabrik Hennecke GmbH & Heinz Söllhöfer* (n 18).

*'to put an end to proceedings pending before a court, provided that the existence of the industrial property right which is the subject-matter of the dispute is genuinely in doubt, that the agreement includes no other clauses restricting competition, and that the no-challenge clause relates to the right in issue.'*<sup>44</sup>

The Court of Justice, however, rejected this opinion in the very next paragraph of judgment, remarking that no distinction should be made between the aims of agreements. The purpose to end litigation should be regarded as no different to any other aim. No-challenge clauses could thus fall within the scope of Art. 101 TFEU. The Court seems to suggest that the anticompetitive potential of such a clause should be determined in isolation from the agreement, even in the case of a patent settlement.<sup>45</sup> This not only contradicts the Court's finding in the same judgment, ie that the legal and economic context in which the agreement takes place should be considered,<sup>46</sup> but also seems barely reconcilable with the possibility of regarding a no-challenge clause as an *ancillary restraint* to the patent settlement.

Ancillary restraints are those kinds of restraints which are necessary to conclude lawful contracts and whose importance is subordinate to the latter.<sup>47</sup> In *Remia v Commission*, the Court of Justice had to consider a situation in which the undertaking selling the business and the undertaking purchasing the business remained competitors on the relevant market. It was therefore necessary to discuss whether non-competition clauses could be part of a lawful sales contract for a business. The Court held that, in this situation, it would be relatively easy for the selling party to "win back" its former customers due to its detailed knowledge about the business and the goodwill which developed a relationship with its customers.<sup>48</sup> If successful, this conduct would not only contradict the very reason for the sale of the business but could potentially also drive the purchaser out of the market, which would in turn actually reduce the number of competitors in the

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<sup>44</sup> Ibid. 14.

<sup>45</sup> Ibid. 19; van der Woude (n 21) 192.

<sup>46</sup> *Case 65/86 Bayer AG v Maschinenfabrik Hennecke GmbH & Heinz Süllhöfer* (n 18) 16.

<sup>47</sup> Pietro Manzini, 'The European rule of reason - crossing the sea of doubt' (2002) 8 *European Competition Law Review* 392, 399.

<sup>48</sup> Giorgio Monti, *EC competition law* (Cambridge University Press, Cambridge, 2007) 33.

market. Following this rationale, the Court found that non-competition clauses can, in principle, have the merits to ensure the intended effect of a business sales contract.<sup>49</sup> Nonetheless, such non-competition clauses must also be strictly limited to that purpose in terms of duration and scope.<sup>50</sup> The general principle of ancillary restraints was applied by the Court of Justice in a number of other instances. In *Pronuptia de Paris*, a case concerning the compatibility of a distribution franchising agreement with Art 101(1), restrictive provisions in the franchising agreement – which concerned the know-how, reputation and common identity of the franchise itself, as well as the protection of its intellectual property rights – were deemed adequate measures to avoid the risk of free-riding by competitors. Hence, the provisions were regarded as ancillary and thus fell outside the scope of Art. 101 TFEU.<sup>51</sup> The Court came to the same conclusion in *Gøttrup-Klim*.<sup>52</sup> The case concerned statutes of a cooperative purchasing association which prevented its members from participating in a competing association. Such a restriction would not necessarily restrict competition, as it was regarded as necessary for ensuring the proper functionality of the cooperative and its ability to maintain its contractual power in relation to producers.<sup>53</sup> In *Métropole Télévision*, the General Court dismissed the ancillary nature of exclusivity clauses to a joint venture.<sup>54</sup> What is noteworthy in this case is not the rejection of the claimant’s argument itself, but rather the General Court’s approach to the ancillary restraint doctrine. The Court discussed the concept of ancillary restraints in detail, holding that ‘it covers any restriction which is directly related and necessary to the implementation of the main operation’.<sup>55</sup> Any restriction that is to be regarded as ‘directly related’ has to be subordinate to the implementation of the main operation and has to have an

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<sup>49</sup> Case 42/84 *Remia v. Commission* [1985] ECR 2545 para. 19.

<sup>50</sup> *Ibid.* para. 20.

<sup>51</sup> Case 161/84 *Pronuptia de Paris* [1986] ECR 353.

<sup>52</sup> Case 250/92 *Gøttrup-Klim and Others Grovwareforeninger v Dansk Landbrugs Grovareselskab* [1994] ECR I-5641.

<sup>53</sup> *Ibid.* para. 40.

<sup>54</sup> Case T-112/99 *Métropole Télévision (M6) & Co. v. Commission* [2001] ECR II-2459.

<sup>55</sup> *Ibid.* para 104.



evident link with it'.<sup>56</sup> To establish whether a restriction is necessary for such implementation, the General Court devised a two stage test.

First, the restriction has to be “objectively necessary” for the implementation of the main operation and, secondly, the restriction has to be proportionate to the main operation. It is important to note that the condition of objective necessity should not be interpreted as a means by which to weigh anticompetitive and procompetitive effects against each other and is therefore not to be regarded as the introduction of a ‘rule of reason’-type analysis within Art. 101(1). The General Court has expressly stated in the judgment that such an analysis can only take place in the specific framework of Art. 101(3).

*‘[This] approach is justified not merely so as to preserve the effectiveness of Article 101(3) of the Treaty, but also on grounds of consistency. As Article 101(1) of the Treaty does not require an analysis of the positive and negative effects on competition of a principal restriction, the same finding is necessary with regard to the analysis of accompanying restrictions.’<sup>57</sup>*

The question is, therefore, not whether the restriction is indispensable to the commercial success of the competitive situation on the relevant market, but rather whether it would be difficult or even impossible to implement the main operation without the restriction, which has to be judged in the specific context of the main operation.<sup>58</sup> The analysis itself must therefore be relatively abstract.<sup>59</sup>

After this condition has been satisfied, the proportionality of the restriction in relation to the main operation has to be examined. The restriction is proportionate if it does not exceed what is necessary to implement the main operation.

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<sup>56</sup> Ibid. para 105.

<sup>57</sup> Ibid. para 108.

<sup>58</sup> Ibid. para 109.

<sup>59</sup> Ibid. para 112.

*'If the duration or the [material and geographic] scope of the restriction exceed what is necessary in order to implement the operation, it must be assessed separately under Article 101(3) of the Treaty'.<sup>60</sup>*

In light of this two-stage test, it has to be established whether it would generally be possible for a patent owner and an alleged patent infringer to conclude a patent settlement *without* a no-challenge clause. In reality, it is highly doubtful that they could. The parties to a patent settlement enter into such an agreement to end costly and time-consuming patent litigation. Yet a patent settlement also creates legal certainty. The patent owner will only enter into a settlement if he is assured that the alleged patent infringer adheres to the agreement, accepts the relevant patent's validity and is unable to challenge the relevant patent yet again in the future. One could argue that a patent settlement that lacks a no-challenge clause defeats the very purpose of the agreement itself. The European Commission's statement concerning patent settlements in its technology transfer guidelines is therefore not surprising:

*'In the context of a settlement and non-assertion agreement, non-challenge clauses are generally considered to fall outside Article 101(1). It is inherent in such agreements that the parties agree not to challenge ex post the intellectual property rights covered by the agreement. Indeed, the very purpose of the agreement is to settle existing disputes and/or to avoid future disputes.'<sup>61</sup>*

This statement arguably recognises that no-challenge clauses are an integral part of patent settlements, which satisfies the first condition of the ancillary restraints test. In the second step, the no-challenge clause has to be proportionate to the patent settlement. It has already been established that the clause is necessary to the main operation. To satisfy the proportionality requirement, the focus has to be on the

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<sup>60</sup> Ibid. para 113.

<sup>61</sup> European Commission, *Guidelines on the application of Article 81 of the EC Treaty to technology transfer agreements* OJ [2004] C 101/2 para. 209.

duration and the scope of the no-challenge clause, which should not go beyond what is necessary to achieve the patent settlement itself.

In terms of duration, the no-challenge clause should not go beyond the life of the patent in question. The patent could not have been challenged until the end of the patent life if the patent's validity had been fully litigated and the patent owner had prevailed. One could also consider determining the proportionate duration of the no-challenge clause, according to the likelihood of the patent owner's success in patent litigation.<sup>62</sup> The assessment of this likelihood is, however, inherently difficult and should generally be avoided by competition authorities as it would involve the "second guessing" of the patent courts.

With regard to its scope, the no-challenge clause should only cover the patents that have been subject to the initial patent litigation. In addition, the geographic scope of the clause should be limited to the scope of the actual patent litigation that has been resolved by the patent settlement. In a case where all these requirements are fulfilled, one should still continue to regard a no-challenge clause as an ancillary restraint to a patent settlement, which should not therefore fall within the scope of Art. 101(1) TFEU.

### **2.1.2. Prevention or distortion of competition**

So far, the old European precedents in relation to trademark delimitation agreements and no-challenge clauses have been discussed and it has been shown that the case law is not suitable for addressing pay for delay settlements under European competition law. It is therefore necessary to go back to square one and consider whether a pay for delay settlement has the object or effect of preventing or distorting competition.

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<sup>62</sup> I.e. if the patent owner's probability of success in front of the court would be by 70 per cent, one could regard a no-challenge clause as proportionate that does not exceed 70 per cent of the remaining time until patent expiry and then grants a royalty-free licence to the patent challenger.

### 2.1.2.1. Restriction by object

Under European competition law, Art. 101(1) TFEU is only infringed if the agreement has as its 'object or effect the prevention, restriction or distortion of competition within the internal market'. Indeed, the question of whether a pay for delay settlement is to be regarded as an infringement by object or by effect is one of the core issues to determine. These two are alternative requirements and should be read disjunctively.<sup>63</sup> The answer to this question determines the level of proof that the European Commission needs to satisfy in order to find an infringement. Agreements that are a restriction by object always fall within the scope of Art. 101(1) TFEU without the need for the European Commission to take into account the actual anticompetitive effects of the agreement. Restrictions *by object* are those that, by their very nature, have the potential to restrict competition within the meaning of Article 101(1).<sup>64</sup>

*'These are restrictions which in light of the objectives pursued by the Community competition rules have such a high potential of negative effects on competition that it is unnecessary for the purposes of applying Article [101(1)] to demonstrate any actual effects on the market. This presumption is based on the serious nature of the restriction and on experience showing that restrictions of competition by object are likely to produce negative effects on the market and to jeopardise the objectives pursued by the Community competition rules.'*<sup>65</sup>

Although an agreement can be restrictive by object, even if its object is not solely anticompetitive but also serves legitimate aims,<sup>66</sup> it is according to the Court of Justice now settled case law that '*regard must be had inter alia to the content of its provisions, the objectives it seeks to attain and the economic and legal context of*

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<sup>63</sup> Case C-56/65 *Société Technique Minière v Maschinenbau Ulm GmbH* [1966] ECR 337 p.249.

<sup>64</sup> Case C-209/07 *Competition Authority v Beef Industry Development Society Ltd* [2008] ECR I-8637 para. 17.

<sup>65</sup> European Commission, *Guidelines on the application of Article 81(3) of the Treaty* [2004] OJ C 101/97 para. 21.

<sup>66</sup> Case C-551/03 *General Motors BV v Commission* [2006] ECR I-3173 para. 64.

which it forms a part'.<sup>67</sup> If these factors are considered, it is sufficient to show that the conduct in question is merely capable of resulting in the prevention, restriction, or distortion of competition within the relevant market.<sup>68</sup> Furthermore, there is no requirement to consider whether the potential negative effect on competition will deprive the final consumer of competitive advantages in terms of supply and price.<sup>69</sup>

Where an agreement is found not to be a restriction by object, the European Commission has to conduct an extensive analysis of the restrictions by effect on the market, which is a much more onerous task.<sup>70</sup> The effects need to be established in the context of factual and legal circumstances which cause it to prevent, restrict or distort competition.<sup>71</sup>

With regard to pay for delay settlements, it has been argued that such settlements should be regarded as restrictions by effect and not by object, as they are by their very nature settlements of patent litigation.<sup>72</sup> It is generally accepted that settlements are a legitimate means by which to end disputes, especially in patent litigation which is costly and time-consuming.<sup>73</sup> Further consideration has been given to the fact that the settlements concern patents which constitute exclusive rights that entitle the holder to exclude infringing products. It would therefore be

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<sup>67</sup> Joint cases C-501/06, C-513/06, C-515/06 and C-519/06 *GlaxoSmithKline Services and Others v Commission and Others* [2009] ECR-I 9291 para.58 citing Joined Cases C-96/82 to C-102/82, C-104/82, C-105/82, C-108/82 and C-110/82 *IAZ International Belgium and Others v Commission* [1983] ECR-I 3369 para.25 and Case C-209/07 *Competition Authority v Beef Industry Development Society Ltd* [2008] ECR I-8637 para. 16 and 21.

<sup>68</sup> Case C-8/08 *T-Mobile Netherlands and Others* [2009] ECR I-4529 para. 31

<sup>69</sup> Case C-501/06 P, *GlaxoSmithKline Services and Others v Commission and Others* [2009] ECR I-9291. The ECJ rejected this finding by the General Court by stating that *'there is nothing in that provision to indicate that only those agreements which deprive consumers of certain advantages may have an anti-competitive object. [...] Article [101 TFEU] aims to protect not only the interests of competitors or of consumers, but also the structure of the market and, in so doing, competition as such.'* Id. at [para. 63].

<sup>70</sup> Richard Whish, *Competition law* (7<sup>th</sup> edn Oxford University Press, Oxford 2012) 120.

<sup>71</sup> Case C-23/67 *Brasserie De Haecht v Wilkin* [1967] ECR 407 p. 415; Case C-234/89, *Delimitis v Henninger Bräu* [1991] ECR I-935 para.14.

<sup>72</sup> van der Woude (n 21).

<sup>73</sup> European Commission (n 1) para 707.

difficult to categorise such settlements as restrictions by object.<sup>74</sup> Furthermore, a large number of settlements identified in the pharmaceutical sector inquiry were found not to restrict generic entry into the market; some even had procompetitive features,<sup>75</sup> and only a minority gave rise to competition concerns.<sup>76</sup> It seems that these considerations led the European Commission to state in its final report that,

*‘any assessment of whether a certain settlement could be deemed compatible or incompatible with EC competition law would require an in-depth analysis of the individual agreement, taking into account the factual, economic and legal background’.*<sup>77</sup>

However, in spite of the abovementioned consideration and the European Commission’s quoted statement from its final report of the pharmaceutical sector inquiry - suggesting the application of an effects-based analysis - does not guarantee that the Commission is not opting for a “by object” analysis after all. Despite having proclaimed the more effects-based approach to Art. 101 TFEU for more than a decade in its regulations and guidelines,<sup>78</sup> the European Commission has framed almost every infringement decision since January 2000 in “object” terms.<sup>79</sup> The underlying reason for this kind of approach is likely to be based on

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<sup>74</sup> Pat Treacy and Sophie Lawrance, ‘Intellectual property rights and out of court settlements’ in Steven D Anderman and Ariel Ezrachi (eds), *Intellectual property and competition law: New frontiers* (Oxford University Press, Oxford, 2011) 293.

<sup>75</sup> European Commission (n 1) para 750, 751.

<sup>76</sup> Ibid. para 743.

<sup>77</sup> Ibid. para 1530.

<sup>78</sup> Commission Regulation 772/2004 on the application of Article 81(3) of the Treaty to categories of technology transfer agreements (2004) OJ L 123; European Commission, *Guidelines on the applicability of Article 81 of the EC Treaty to horizontal cooperation agreements* [2011] OJ C 11 ; European Commission, *Guidelines on the application of Article 81(3)* (n 65); European Commission, *Guidelines on the Application of Article 81 of the EC Treaty to Technology Transfer Agreements* [2004] OJ C 101/2; European Commission, *Guidelines on Vertical Restraints* [2010] OJ C 130/01; Commission Regulation (EC) No 2790/1999 on the application of Article 81(3) of the Treaty to categories of vertical agreements and concerted practices (1999) OJ L 336 ; Commission Regulation (EC) 2659/2000 on the application of Article 81(3) of the Treaty to categories of research and development agreements (2000) OJ L 304; Commission Regulation 2658/2000 on the application of Article 81(3) of the Treaty to categories of specialisation agreements (2000) OJ L 304.

<sup>79</sup> Damien M Gerard, ‘The Effects-Based Approach Under Article 101 TFEU and its Paradoxes: Modernisation at War with Itself?’ in Jacques Bourgeois (ed), *Ten years of effects-based approach in EU competition law: State of play and perspectives* (Bruylant, Bruxelles op. 2013) 38. 17 out of 18

strategic considerations, as it is a lot easier to bring a successful case when there is no requirement to show the anticompetitive effects of an agreement. The European Commission regularly justifies this approach by stating that an “object” restriction should not be seen as a “per se” style infringement as in the United States. Even an “object” restriction would allow for justifications which make the presumption a rebuttable one. Yet it has been correctly stated that such an argument is only valid if a rebuttal is a *‘reality rather than a theoretical possibility’*.<sup>80</sup> Although the European Court of Justice has previously considered that object restrictions should be theoretically open to justification, it has *‘never in recent memory overturned a finding that they were not’*.<sup>81</sup>

The European Commission seems to have reverted to this *modus operandi* in its *Lundbeck* decision – the first European decision in relation to pay for delay settlements. Although the press release issued by the European Commission remains silent with regards to the type of restriction that the Commission has found, it became evident on 9 November 2013 that the decision was based on restrictions by object. On this day, a number of generic companies and Lundbeck itself appealed the decision to the General Court, with one of the main arguments being that the European Commission had committed a manifest error of assessment by finding that the pay for delay settlement constituted a restriction of competition ‘by object’.<sup>82</sup> In another pay for delay case, the European Commission imposed a fine of €16 million on Johnson & Johnson and Novartis.<sup>83</sup> According to trade press, it seems that a restriction by object was also found in this case, but the parties have decided not to appeal the decision.<sup>84</sup> Thus, it remains to be seen whether it can be justifiable to find a restriction by object with regard to the actual

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infringement decisions were regarded as object restrictions which included all vertical cases and 8 out of 9 horizontal cases.

<sup>80</sup> Alison Jones, ‘Left behind by modernisation? Restrictions by object under Art. 101 (1)’ (2010) 6 European Competition Journal 649, 663.

<sup>81</sup> Gerard (n 79) 40.

<sup>82</sup> Case T-460/13 *Ranbaxy Laboratories and Ranbaxy (UK) v Commission* (n 6); Case T-472/13 *H. Lundbeck and Lundbeck v Commission* (n 6); Case T-470/13 *Merk v. Commission* (n 6); Case T-471/13 *Xellia Pharmaceuticals and Zoetis Products v Commission* (n 6).

<sup>83</sup> European Commission (n 5).

<sup>84</sup> Dechert LLP, ‘OnPoint: A legal update from Dechert’s Antitrust/Competition Group’ (2013) <http://sites.edechert.com/10/2122/december-2013/pay-for-delay-agreements-do-not-pay-off.asp#page=1>.

agreement based on the legal and economic context of the actual market in question.

In light of the aforementioned, the European Commission should generally resist the temptation to regard pay for delay settlements as restrictions by object. It is important to keep in mind that the anticompetitive potential of pay for delay settlements in Europe is likely to be reduced when compared to the United States. As has been pointed out above,<sup>85</sup> there does not exist in Europe a regulatory bottleneck akin to the Hatch Waxman Act which facilitates market foreclosure. In contrast, in the United States, even with the increased anticompetitive potential the US Supreme Court has opted in its pay for delay judgment *FTC v. Actavis*<sup>86</sup> for a rule of reason approach, which is discussed in detail in the next section.

Regarding pay for delay settlements in Europe as restrictions by object also increases the potential for Type I errors and over-enforcement. Depending on the actual definition of pay for delay settlements, patent settlements with a value transfer from the brand company to the generic company which are followed by the exit of the generic company from the market could fall foul of Art 101(1) TFEU. Such a payment could, however, be perfectly reasonable. It might settle litigation costs or may constitute a payment for services rendered by the generic company. An indicator for anticompetitive conduct could be the level of the payment. However, such an evaluation cannot take place for object restrictions.

Two exceptions to this general rule could nonetheless be considered. One is the case when the agreement clearly exceeds the scope of the patent; for example, when the agreement prevents the generic company from entering the market after the protection of the relevant patent has elapsed. This type of conduct has also been accepted as being anticompetitive by the US jurisprudence prior to the US Supreme Court's decision in *Acatvis*.<sup>87</sup> The second exception could be a situation in

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<sup>85</sup> See chapter III sec. 2.3.2.

<sup>86</sup> *FTC v. Actavis* 133 S.Ct. 2223 (2013).

<sup>87</sup> The Federal Circuit which applies the "scope of the patent test" regarded such settlements that go beyond the patent life as anticompetitive. *In re Ciprofloxacin Hydrochloride Antitrust litigation* 544 f.3d 1323 (Fed. Cir. 2008), cert. denied, 129 S.Ct. 2828 (2009); *Valley Drug Co. v. Geneva*



which the parties are aware of facts that would remove the uncertainty regarding the outcome of patent litigation to the point at which the European Commission would no longer have to second-guess the validity of the patent at issue. One possibility could be the discovery of internal documents that provide evidence that the patentee was aware of patent's invalidity.<sup>88</sup> Apart from these noted exceptions, pay for delay settlements should not be subjected to a "restriction by object" analysis.

#### **2.1.2.2. Restriction by effect**

In light of this finding, this section therefore analyses pay for delay settlements by employing an effects-based approach. After having set out the basic principles of such an analysis based on the European Commission's relevant guidance papers and the relevant case law, the section addresses what has so far been regarded as the major legal issue of an effects-based analysis of pay for delay settlements; namely, the need to evaluate the validity of the underlying patent. Acknowledging this legal issue, it will be established whether the US Supreme Court's judgment in *Actavis* can be used as guidance to overcome this hurdle in the European context, as the Supreme Court addressed the very same issue – the antitrust scrutiny of pay for delay settlements without an inquiry into the validity of the underlying patent. Following a detailed description of the US judgment, the remainder of this section develops a novel structured effects-based analysis inspired by the rationale of the US Supreme Court's judgment in *Actavis* that circumvents this issue of patent validity, without being over-inclusive with regard to patent settlements that lack a value transfer from the brand company to the generic company.

Determining whether an agreement amounts to a restriction by effect requires proof of the likely negative impact of the agreement on inter- or intra-brand competition. According to the European Commission's Guidelines, the agreement:

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*Pharmaceuticals, Inc* 344 F.3d 1294, (11th Cir. 2003); *In re Tamoxifen Citrate Antitrust Litigation* 466 F.3d 187 (2nd Cir. 2005).

<sup>88</sup> Bill Batchelor, 'EC tones down its final report into the pharma sector, but ramps up enforcement activity' (2010) 31 European Competition Law Review 16; Treacy and Lawrance (n 74) 293.

*'must affect actual or potential competition to such an extent that on the relevant market negative effects on prices, output, innovation or the variety or quality of goods and services can be expected with a reasonable degree of probability'.<sup>89</sup>*

In order to find that an agreement has an actual or potential anticompetitive effect, the European Commission must determine whether the parties to the agreement have a degree of market power and whether the agreement contributes to the strengthening or maintenance of this market power.<sup>90</sup> This requires the consideration of the economic and legal context in which the agreement takes place.<sup>91</sup> In addition, the Guidelines also provide for a counterfactual analysis, questioning whether the restriction to competition would not have existed without the agreement.<sup>92</sup>

This counterfactual analysis has so far posed the question of what the outcome would have been without the settlement agreement. Treacy and Lawrance argue that this would require the assessment of the probable outcome of the settled patent litigation and, thus, an estimation of the strength of the litigated patent.<sup>93</sup> Such an inquiry by the European Commission would not only pre-judge the finding of specialist patent courts,<sup>94</sup> but would also be inherently difficult. The European Commission would only be able to infer generic entry but for the pay for delay, if the disputed patent is weak. The definition of "weakness" also raises difficulties as

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<sup>89</sup> European Commission, *Guidelines on the application of Article 81(3)* (n 65) para. 24.

<sup>90</sup> *Ibid.* para. 25.

<sup>91</sup> Cases T-374/75, 384, 388/94 *European Night Services v Commission* [1998] ECR II-3141 para. 136; Case T-328/03, *O2 (Germany) GmbH & Co OHG v Commission* [2006] ECR II-1231 para. 66.

<sup>92</sup> European Commission, *Guidelines on the application of Article 81(3)* (n 65) para. 18; Case C-234/89, *Delimitis v Henninger Bräu* [1991] ECR I-935 para. 23; Case T-328/03, *O2 (Germany) GmbH & Co OHG v Commission* (90) para. 68.

<sup>93</sup> Treacy and Lawrance (n 74) 295.

<sup>94</sup> *Ibid.* 295.

the European Commission would have to decide at which probability of success the companies would have to refrain from settling.<sup>95</sup>

These considerations and arguments are not unique to the European context. The very same issues had to be addressed by the US Supreme Court in its *Actavis* judgment. The following subsection therefore discusses the US judgment itself in order to establish whether inspiration can be drawn from Supreme Court's analysis.

#### **2.1.2.2.1. *FTC v Actavis* and the FTC's amicus curiae brief in *Effexor XR***

This section discusses the recent US Supreme Court decision in *Actavis* and the FTC's amicus curiae brief in *Effexor XR*, in which the FTC argues that the *Actavis* rule should be extended to non-cash payments as a form of value transfer. Drawing conclusions from the judgment and the amicus curiae brief might help to develop a European approach to pay for delay settlements.

In *Actavis*, the US Supreme Court for the first time examined the legality of pay for delay settlements. The FTC had applied for writ of certiorari<sup>96</sup> in earlier pay for delay settlement cases but the US Supreme Court had refused to grant it until the present case.<sup>97</sup> The reason for the Supreme Court's change of heart was the fact that the Federal Trade Commission managed to create a so-called "split circuit". This refers to a situation where several circuit courts come to different decisions on the same issue. In the case of pay for delay settlements, the split was achieved between, on the one side, the Second Circuit,<sup>98</sup> Eleventh Circuit<sup>99</sup> and Federal

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<sup>95</sup> Ibid. 298.

<sup>96</sup> Writ of certiorari is a petition for judicial review of an important matter by the US Supreme Court. The petition is granted by judicial discretion and US Supreme Court considers such review, *if for example 'a United States court of appeals has entered a decision in conflict with the decision of another United States court of appeals on the same important matter; has decided an important federal question in a way that conflicts with a decision by a state court of last resort; or has so far departed from the accepted and usual course of judicial proceedings, or sanctioned such a departure by a lower court, as to call for an exercise of this Court's supervisory power.'* Rule 10(a) of the Rules of the United States Supreme Court.

<sup>97</sup> *In re Ciprofloxacin Hydrochloride Antitrust litigation* 544 f.3d 1323 (Fed. Cir. 2008), cert. denied, 129 S.Ct. 2828 (2009).

<sup>98</sup> *In re Tamoxifen Citrate Antitrust Litigation* 466 F.3d 187 (2nd Cir. 2005).

<sup>99</sup> *In re Ciprofloxacin Hydrochloride Antitrust litigation* (n 97).

Circuit<sup>100</sup> who essentially applied the so-called “scope of the patent” test and, on the other side, the Third Circuit<sup>101</sup> who treated pay for delay settlements as “presumptively unlawful”. According to the “scope of the patent” test,

*‘absent sham litigation or fraud in obtaining the patent, a pay for delay settlement is immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent.’<sup>102</sup>*

The finding that pay for delay settlements should be immune from antitrust liability was based on the assumption that such liability would undermine the patent incentive and would stifle innovation.<sup>103</sup> Additionally, the courts stressed the general importance of the settlements, especially in patent infringement litigation.<sup>104</sup> The only noted exception under which the court has to consider the patent’s validity in an antitrust analysis is in the case of fraud in front of the patent office or in the case of sham litigation.<sup>105</sup> In the event of such conduct, the agreement’s restrictive effect on competition would be regarded as beyond the exclusionary scope of the patent.<sup>106</sup>

The Third Circuit expressly rejected the “scope of the patent” test, holding pay for delay settlements to be a *prima facie* unreasonable restraint of trade. The Court based this finding on a number of reasons. First of all, it rejected the notion that the statutory presumption of validity in patent law is a substantive right of the patent holder; rather, it constitutes a procedural device which puts the burden of proof on

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<sup>100</sup> *Federal Trade Commission v. Watson Pharmaceuticals Inc.* 677 F.3d 1298 (11th Cir. 2012).

<sup>101</sup> *In re K-Dur Antitrust Litigation* 686 F. 3d 197 (3d Cir. 2012).

<sup>102</sup> *Federal Trade Commission v. Watson Pharmaceuticals Inc.* (n 100) 1312.

<sup>103</sup> *Valley Drug Co. v. Geneva Pharmaceuticals, Inc* 344 F.3d 1294, (11th Cir. 2003) 1311 & n.2, affirmed in *Schering-Plough Corp. v. FTC* 402 F.3d 1056, (11th Cir. 2005) 1065-66.

<sup>104</sup> *Schering-Plough Corp. v. FTC* 402 F.3d 1056, (11th Cir. 2005) 1072-73; *In re Ciprofloxacin Hydrochloride Antitrust litigation* (n 98) 1333.

<sup>105</sup> For a detailed analysis of this type of conduct see chapter II sec. 6.1.1 discussing the Walker Process Doctrine.

<sup>106</sup> *In re Ciprofloxacin Hydrochloride Antitrust litigation* (n97) 1336; *Valley Drug Co. v. Geneva Pharmaceuticals* (n 103) 1308 & n.21; *In re Tamoxifen Citrate Antitrust Litigation* (n 98) 213; *Schering-Plough Corp. v. FTC* (n 104) 1068.

the party that is challenging patent validity.<sup>107</sup> Furthermore, pay for delay settlement cases do not concern patent validity but rather patent infringement, in which case the burden of proof is on the patent holder – hence, the argument based on the presumption of validity is misguided.<sup>108</sup> Secondly, the Court emphasises public policy considerations on which not only the patent system is based<sup>109</sup> but also the Hatch Waxman Act, which is aimed at providing incentives to increase competition in the pharmaceutical sector through patent challenges by generic companies. The Court directly quoted congressional statements made in relation to the Bill which underlines the intention of Congress to provide consumers with cheaper generics by encouraging generic companies to challenge patents that they regard as weak or invalid.<sup>110</sup> This public policy consideration is undermined by the “scope of the patent” test.<sup>111</sup> Following these considerations, the Court remanded the case and directed the District Court to:

*‘apply a quick look rule of reason analysis based on the economic realities of the pay for delay settlement [regarding a reverse payment] as prima facie evidence of an unreasonable restraint of trade, which could be rebutted by showing that the payment (1) was for a purpose other than delayed entry or (2) offers some pro-competitive benefit.’*<sup>112</sup>

The US Supreme Court’s majority decision written by Justice Breyer, however, rejected both propositions, the scope of the patent test and the quick look rule of reason approach and instead struck the middle-ground, ruling that a full rule of reason analysis would be appropriate in the case of pay for delay settlements.

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<sup>107</sup> *In re K-Dur Antitrust Litigation* (n 101) 214.

<sup>108</sup> *Ibid.*

<sup>109</sup> “It is the public interest which is dominant in the patent system and [...] the right to challenge [a patent] is not only a private right to the individual, but it is founded on public policy which is promoted by his making the defence, and contravened by his refusal to make it.” *In re K-Dur Antitrust Litigation* (n 101) 216.

<sup>110</sup> *In re K-Dur Antitrust Litigation* (n 101) 217.

<sup>111</sup> *Ibid.*

<sup>112</sup> *Ibid.* 218.

The decision strongly dismissed the “scope of the patent” test. First of all the Court accepted the 11<sup>th</sup> Circuit’s finding that the agreement’s ‘anticompetitive effects fall within the scope of the exclusionary potential of the patent’,<sup>113</sup> but it disagreed with the suggestion that this fact could also ‘immunize the agreement from antitrust attack’.<sup>114</sup> It further indicated that patent and antitrust policy are both relevant in determining the “scope of the patent monopoly” – and consequently antitrust immunity – that is conferred by a patent.<sup>115</sup> Yet, with regard to pay for delay settlements which according to the FTC tend to have significant adverse effects on competition, the “scope of the patent” test simply refers to what the holder of a valid patent can do and does not answer the antitrust question. The Court therefore found that:

*‘it would be incongruous to determine antitrust legality by measuring the settlement’s anticompetitive effects solely against patent law policy rather than by measuring them against procompetitive antitrust policies as well.’<sup>116</sup>*

At the same time, the Court rejected a “quick look” analysis proposed by the FTC which would have been based on a presumption of illegality. The Court cited its decision in *California Dental* and held:

*‘that abandonment of the “rule of reason” in favour of presumptive rules (or a “quick look” approach) is appropriate only where “an observer with even a rudimentary understanding of economics could conclude that the arrangements in question would have an anticompetitive effect on consumers and markets.”<sup>117</sup>*

Applying these findings to the case at hand, the Court decided that the criteria for a “quick look” analysis of pay for delay settlements had not been met, as the

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<sup>113</sup> *Federal Trade Commission v. Watson Pharmaceuticals Inc.* (n 100) 1312.

<sup>114</sup> *FTC v. Actavis* (n 86) 2230.

<sup>115</sup> *Ibid.* 2231.

<sup>116</sup> *Ibid.* 2230-31.

<sup>117</sup> *Ibid.* 2242; quoting *California Dental Ass’n v. FTC* 526 U.S. 756 (1999) 770.

likelihood of anticompetitive effects arising from pay for delay settlements depends on a number of factors such as '[the] size [of the payment], its scale in relation to the payor's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification.'<sup>118</sup> The Court opted for a full rule of reason analysis because of this complexity.

A full-scale rule of reason analysis traditionally requires definition of a relevant market, proof of market power and the existence of anticompetitive effects, meaning the existence of a restraint that threatens to reduce output or increase prices without being justified by efficiencies or some other redeeming virtue.<sup>119</sup> The burden of proof in a rule of reason analysis is on the plaintiff. However, the Court determined at length the level of evidence the plaintiff would have to provide in order to satisfy the burden of proof.<sup>120</sup> It found that because of the circumstances surrounding pay for delay settlements the plaintiff would only be required to provide more abbreviated proof than normally required by a rule of reason analysis<sup>121</sup> – thereby also addressing the question of how to evaluate the antitrust concern without having to rule on the relevant patent's validity. The Court found that this kind of abbreviated proof was sufficient in relation to market power as well as the anticompetitive effect of pay for delay settlements.

Addressing the market power issue the Court found that the

*'size of the payment from a branded drug manufacturer to a prospective generic is itself a strong indicator for power – namely the power to charge prices higher than the competitive level'.<sup>122</sup>*

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<sup>118</sup> Ibid. 2242.

<sup>119</sup> Herbert J Hovenkamp, 'Anticompetitive Patent Settlements and the Supreme Court's Actavis Decision' (2014) 15 Minnesota Journal of Law, Science and Technology 3. 6

<sup>120</sup> *FTC v. Actavis* (n 86) 2234-7.

<sup>121</sup> Ibid. 2238.

<sup>122</sup> Ibid. 2236.

A firm without such power would not be likely to pay 'large sums to induce others to stay of the market'.<sup>123</sup> This finding is based on the rationale that, in a competitive market, the incentive of keeping a competitor out of the market should be close to zero. In a highly competitive market, price-cost margins are very low and this situation cannot be improved by keeping competitors out of the market.<sup>124</sup> However, this incentive rises with the increase in price-cost margins. A firm with market power typically enjoys high profit margins and therefore has an incentive to defend these by excluding competitors from the market.<sup>125</sup> In the case of a time-limited monopoly, such as patents, the rational patentee would pay no more than the anticipated monopoly return over the remaining period of patent protection.<sup>126</sup> Thus the level of market power is a function of the size of the payment made to the generic - The bigger the size of the payment, the higher the market power.

Furthermore, the Court also noted that the size of the payment can also be an indicator for the anticompetitive harm caused by the pay for delay settlement and can act as '*a workable surrogate for a patent's weakness*'.<sup>127</sup> According to the Court, it was therefore also unnecessary to evaluate the validity of the patent itself as part of the rule of reason analysis. It agreed with the FTC that the rationale behind a payment of this size cannot in every case be traditional settlement considerations.<sup>128</sup> It should rather be seen as evidence that the patentee is not confident in the strength of the patent in question and seriously doubts that it would prevail in patent litigation.<sup>129</sup> According to the Court, a settlement in such a situation reduces the extent or likelihood of competition. The Court also indicated that a small reduction of likely competition is sufficient by stating that:

*'the owner of a particularly valuable patent might contend, of course, that even a small risk of invalidity justifies a large payment. But, be that as it may, the*

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<sup>123</sup> Ibid. 2236.

<sup>124</sup> Aaron Edlin and others, 'Activating Actavis' (2013) 38 Antitrust Health Care Chronicle 16.

<sup>125</sup> Ibid.

<sup>126</sup> Hovenkamp (n 119) 24.

<sup>127</sup> *FTC v. Actavis* (n 86) 2236.

<sup>128</sup> Ibid. 2233.

<sup>129</sup> Ibid. 2236.



*payment (if otherwise unexplained) likely seeks to prevent the risk of competition. And, as we have said, that consequence constitutes the relevant anticompetitive harm.*<sup>130</sup>

Nonetheless, the Court conceded that payments might reflect legitimate settlement considerations, such as avoiding litigation costs or attaining fair value for services provided. Yet this possibility should not prevent the FTC from scrutinising the settlement. Ultimately, a district court should be able to examine the size of the payment, its likely anticompetitive effects and its potential justifications in the future.<sup>131</sup>

Judging by these considerations, it is possible to set out the following test to determine whether a pay for delay settlement restricts competition:<sup>132</sup>

(1) The plaintiff has to prove that the relevant payment to the generic company is large by:

- a. Valuing the consideration flowing from the patentee to the alleged infringer, and
- b. Deducting the avoided litigation costs for the patentee.

If this net payment is positive it may be understood as a *prima facie* restriction of competition by means of delaying entry.

(2) The defendant then has the burden of proof for showing that this net payment can be explained as payment for services or goods rendered by the alleged infringer to the patentee as part of the same transaction.

In the wake of the US Supreme Court's judgment in *Actavis*, the Federal Trade Commission has now sought to extend the *Actavis* rule to non-cash payments. In recent months, the FTC has filed two amicus curiae briefs; one in the District Court

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<sup>130</sup> Ibid.

<sup>131</sup> Ibid. 2236.

<sup>132</sup> Edlin and others (n 124) 17, 18.

for the district of New Jersey,<sup>133</sup> and one in the District Court for the eastern district of Pennsylvania.<sup>134</sup> Both cases concern patent settlements between a brand company and a first-filing generic company that do not involve pay for delays in monetary terms but rather in terms of non-cash contributions for the generic company. The respective brand companies agreed as part of the settlement not to launch an authorised generic version of the brand drug during the period of generic exclusivity granted by the Hatch Waxman Act. In the case of *Effexor XR*, a “no-authorized-generic commitment”<sup>135</sup> by Wyeth Pharmaceuticals induced TEVA, a generic manufacturer, to abandon its patent challenge and refrain from selling its generic version of Effexor XR for a two-year period.<sup>136</sup> According to the FTC, this lack of generic competition during the generic exclusivity period has a significant impact on the generic company’s profits.<sup>137</sup> The FTC therefore argues that the Supreme Court in *Actavis* did not limit the applicability of the *Actavis* rule to monetary payment and claims that:

*‘accepting the defendants’ claim of immunity whenever patentees use vehicles other than cash to share the profits from an agreement to avoid competition elevates form over substance, and it would allow drug companies to easily circumvent the ruling in Actavis, at great cost to consumers.’*<sup>138</sup>

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<sup>133</sup> *In re Effexor XR Antitrust Litigation, Lead case no.: 3:11-cv-05479* (14 August 2013) Federal Trade Commission brief as amicus curiae.

<sup>134</sup> *In re: Wellbutrin XL Antitrust Litigation, Case no.: 2:08 -cv-2431, 2433* (26 September 2013) Federal Trade Commission brief as amicus curiae.

<sup>135</sup> Authorised generics do not need separate drug approval from the FDA, as they are identical to the brand drug. Thus brand companies can compete with the first-filing generic company even during the period of generic exclusivity.

<sup>136</sup> *In re Effexor XR Antitrust Litigation* (n 133) 1.

<sup>137</sup> Federal Trade Commission, *Authorized Generic Drugs: Short-Term Effects and Long-Term Impact*(2011) <<http://www.ftc.gov/reports/authorized-generic-drugs-short-term-effects-long-term-impact-report-federal-trade-commission>> “[d]ue to market share and pricing erosion at the hands of the authorized player, we estimate that the profits for the ‘pure’ generic during the exclusivity period could be reduced by approximately 60% in a typical scenario.” *Id.* at [ 81]. In another case it was estimated that an authorised generic reduced the generic company’s revenues by approximately \$400 million. *In re Effexor XR Antitrust Litigation* (n 133) 12.

<sup>138</sup> *In re Effexor XR Antitrust Litigation* (n 133) 2.

In the light of this argument the FTC proposes in its briefs as amicus curiae to extend the *Actavis* rule to non-cash payment by asking:

- (1) Whether the alleged payment is something that a generic challenger could not have obtained had it won the litigation, and
- (2) Whether the parties are sharing monopoly profits preserved by avoiding competition.<sup>139</sup>

A “no-authorized-generic commitment” is a benefit that a generic company could not obtain by prevailing in patent litigation. Even if the generic company were to win the patent litigation, the brand company would nonetheless have the right to compete against the generic company by entering the market with an authorised generic, as patent invalidity or non-infringement does not affect the right to market an FDA-approved drug.<sup>140</sup>

This extension of the judgment in *Actavis* seems to be sensible. However, it remains to be seen how the District Courts will decide this.

#### **2.1.2.2.2. Application of the rationale in *FTC v Actavis* in the European context**

Following the discussion of the majority opinion of the US Supreme Court, the question is whether the issues surrounding patent validity, including the pre-judging of patent courts, could also be avoided in the European context by applying the rationale of the US Court. As set out above, the Supreme Court infers not only market power but also the anticompetitive effect from the size of the payment that is directed from the brand company to the generic company and, therefore, it avoids an assessment of the validity of the patent in question.

Taking the same approach with regard to market power in the European context should not be problematic. Market power as a concept is defined as the ability to profitably raise prices to a supra-competitive level, to profitably maintain output in terms of product quantities, product quality and variety, or to innovate

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<sup>139</sup> Ibid. 8; *In re: Wellbutrin XL Antitrust Litigation* (n 134) 6.

<sup>140</sup> *In re Effexor XR Antitrust Litigation* (n 133) 15; *In re: Wellbutrin XL Antitrust Litigation* (n 134) 12.

below competitive levels for a period of time.<sup>141</sup> Similarly to the situation in the United States, the brand company should only be willing to make a payment to the generic company that exceeds litigation costs and costs for services rendered, if the brand company's intention is to protect its high price-cost margins. However, such high price-cost margins are only likely to occur in markets that are not competitive. It should therefore be possible, by implication, to infer market power through the willingness to defend high price-cost margins by way of assessing the size of the payment.

However, inferring anticompetitive effects from the size of the payment is more problematic in the European context and must therefore be discussed in detail. It is important to consider the regulatory context in which pay for delay settlements take place on both sides of the Atlantic and factor in the regulatory differences. In the United States, the relevant market can be effectively foreclosed by a single pay for delay settlement. As has been explained above, the Hatch Waxman Act has created a regulatory bottleneck.<sup>142</sup> The FDA, which grants pharmaceutical marketing authorisation, is only allowed to grant subsequent generic applications once the first-filing generic company has marketed its generic version of the brand drug for 180 days. It is thus possible for the brand company to foreclose the market by inducing the generic company not to market its generic drug for x-amount of time while also postponing the period of generic exclusivity which is, in turn, the trigger for subsequent generic applications to the FDA. In light of this regulatory bottleneck, it is acceptable to infer anticompetitive effects from the size of the payment, due to the causal link between the size of the payment from the brand company to the generic company and the delay of generic entry which leads to the foreclosure of the market.

However, such a regulatory bottleneck does not exist in the European context. Pharmaceutical regulators in Europe base their decision of generic approval solely on health and safety considerations and do take economic factors such as patents into account. The regulator is not limited in the number of generic

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<sup>141</sup> European Commission, *Guidelines on the applicability of Article 101 of the Treaty on the Functioning of the European Union to horizontal co-operation agreements* (2011) para. 39.

<sup>142</sup> For the discussion of the peculiarities of the Hatch Waxman Act see chapter III sec. 2.3.1.

drug approvals it can issue for the same brand drug prior to patent expiry, as long as all applications are compliant with the relevant health and safety regulations. Paying off a single generic company does not therefore guarantee that the brand company will be protected from competition for the duration of that agreement. Other generic companies are not prevented from entering the market, although they run the risk of being sued for patent infringement by the brand company. Ultimately, this also means that one cannot presume that an anticompetitive foreclosing effect results from the agreement between the brand company and a single generic company that agrees not to enter the market or to delay its entry. It is therefore also not appropriate to infer an anticompetitive effect solely on the basis of the size of the payment within this agreement, just as in the United States.

That said, this should also not lead to the conclusion that the anticompetitive effects of pay for delay settlements in Europe can only be shown by means of examining the validity of the patent. The assessment of the regulatory framework in Europe does not suggest that it is impossible for a single pay for delay settlement to result in anticompetitive foreclosure effects. The lack of a regulatory bottleneck similar to the Hatch Waxman Act should not be equated with a lack of potential for anticompetitive foreclosure in Europe. The manifestation of such an effect is, rather, dependent on the actual market structure and the competitive environment in the relevant market. Imagine a scenario where a number of generic companies are present in a given market, but only one of these companies has the financial and technical means to realise the economies of scale that are necessary to profitably market the generic version of a branded drug. In this case, the remaining generic companies would not be able to enter the market to exert competitive pressure on the brand company despite the lack of any legal or regulatory absolute barriers to entry and the ability to apply for market authorisation. In effect, this scenario would lead to at least the same level of anticompetitive effects witnessed in the United States. Indeed, the situation could be even more detrimental to competition due to the lack of potential competitors which are foreclosed by the agreement.

It should therefore be possible to infer anticompetitive foreclosure effects from the size of the payment *in addition to* an assessment of the competitive environment within the relevant market (ie the number of potential generic competitors).

Such an analysis would not be dissimilar to the ECJ's judgment in *Delimitis v Henninger Bräu*,<sup>143</sup> which epitomises the EU court's approach to restrictions by effect. In this case, the Court had to assess whether exclusive beer supply agreements between a brewery and public houses amounted to a restriction by effect because of their potential to foreclose the market. Having highlighted the general pro-competitive features of such beer supply agreements,<sup>144</sup> the Court set out a test to establish whether the beer supply agreement in question led to an anticompetitive foreclosure of the relevant market. In order to establish the potential foreclosure, the Court deemed it necessary to define the relevant market. The Court then went on to examine whether it was difficult for competitors to gain access to the market in the light of the economic and legal context of the agreement at issue.<sup>145</sup> The market in *Delimitis v Henninger Bräu* was comprised of a multitude of similar beer supply agreements, which led the Court to find that these agreements could have a cumulative effect on competition. Because of this cumulative effect on competition, it was therefore necessary to assess whether the agreement in question had made a significant contribution to the foreclosure of the market brought about by the totality of those agreements in their legal and economic context. In general terms, the judgment in *Delimitis v Henninger Bräu* has thereby established that even vertical agreements with pro-competitive features can potentially give rise to significant anticompetitive effects when considered in their legal and economic context in the relevant market.

The Court's judgment in *Delimitis v Henninger Bräu* therefore shows that it is possible to have a "structured approach" to an effects-based analysis under Art. 101(1) TFEU. In addition, it has been suggested that it should generally be possible to have a truncated analysis in "restriction by effect" cases, in which the actual

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<sup>143</sup> Case C-234/89, *Delimitis v Henninger Bräu* [1991] ECR I-935.

<sup>144</sup> *Ibid.* para. 10,11.

<sup>145</sup> *Ibid.* para. 27

anticompetitive effects are not measures but inferred by an evaluation of circumstantial evidence.<sup>146</sup>

The structured analysis in *Delimitis v Henninger Bräu* and the fact that the EU courts are familiar with the possibility of employing a truncated analysis lend themselves well to the situation of pay for delay settlements in Europe. The discussion of the theory of harm of pay for delay settlements above has shown that a single pay for delay settlement in a European market that includes a number of potential generic competitors is likely to have a significantly lower anticompetitive potential than the same scenario in the United States.<sup>147</sup> A viable option would be for the brand company to pay-off all possible generic entrants so that they do not enter the market at the same time, thereby foreclosing the market. Yet this scenario might change in light of the actual competitive environment of the relevant market.

This thesis therefore proposes to extend the *Actavis* test by an additional criterion to accommodate the regulatory differences in the European setting. Additionally, it would also appear sensible to follow the FTC's approach in its amicus curiae briefs regarding the extension of pay for delay settlements to non-cash payments. Due to the increased scrutiny of the pharmaceutical sector and the attention that pay for delay settlements receive in Europe, it is likely that the companies will try to hide or disguise the value transfer. Monetary payments are likely to decrease, whereas the focus will shift to other types of value transfers such as

*'distribution agreements or a "side-deal" in which the originator company grants a commercial benefit to the generic company, for example by allowing it to*

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<sup>146</sup> See Andreas P Reindl, 'Resale price maintenance and article 101: Developing a more sensible analytical approach' (2011) 33 Fordham International Law Journal 1300, 1309-1313 highlighting this point by reference to the European case law on information exchange among competitors and the analytical framework used by the courts. E.g. in the case of *Case C-7/59 John Deere, Ltd. v. Commission* [1998] ECR I-3111. the ECJ accepted the evidence for actual anticompetitive effects might not be required, if a careful evaluation of circumstantial evidence in relation to information exchange between competitors can be provided; at [para 78, 90]

<sup>147</sup> See discussion in chapter III sec. 2.3.2 and 2.3.3.

*enter the market before patent expiry in another geographical area or by allowing market entry with another product marketed by the originator company.*<sup>148</sup>

The European Commission also confirms that the list of possible value transfers is non-exhaustive,<sup>149</sup> which is understandable. A set list of possible value transfers would only provide the opportunity to circumvent such a transfer. For the same reason, it is sensible to broaden the proposed test to non-monetary value transfers from the brand company to the generic company.

The proposed test is the following:

- (1) The European Commission has to define the relevant market and examine the competitive environment within the market.
- (2) The European Commission must also prove that the relevant value transfer to the generic company is large either:
  - (a) In the case of a monetary payment by –
    - (a) Valuing the consideration flowing from the patentee to the alleged infringer, and
    - (b) Deducting the avoided litigation costs for the patentee,
  - OR*
  - (b) In the case of a non-monetary value transfer by –
    - a. Valuing the consideration flowing from the patentee to the alleged infringer, and
    - b. Determining whether this value transfer could have been achieved by successful patent litigation.
- (3) There is to be a presumption of a *prima facie* restriction of competition by means of delaying entry, if:

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<sup>148</sup> European Commission, *3rd Report on the Monitoring of Patent Settlements (period: January-December 2011)* (2012) <[http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/patent\\_settlements\\_report3\\_en.pdf](http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/patent_settlements_report3_en.pdf)> recital 9.

<sup>149</sup> *Ibid.*



- (a) this net payment is positive *or* the value transfer could not have been achieved by means of patent litigation, and
  - (b) the agreement at issue has made a significant contribution to the actual or potential foreclosure of the market based on the economic and legal context.
- (4) The investigated companies then have the burden of proof to show that this net payment or the value transfer can be justified as a payment for goods/services rendered by the alleged infringer to the patentee as part of the same transaction.

This test is not believed to be over-inclusive. It takes into consideration the efficiency considerations of patent settlements and the actual conditions on the relevant market. It does not dis-incentivise patent settlements and does not condemn settlements that have no appreciable anticompetitive effect on the market. Even if the two parties enter into a pay for delay settlement that included a positive net payment, the agreement is not likely to produce anticompetitive effects if a number of equally efficient generic competitors are able to enter the market – hence the need to cumulatively satisfy the criteria under (2)(a) in order to infer anticompetitive effects from the positive net payment. The test is also not over-burdening the parties involved as it is assumed that the parties have the best knowledge of the competitive environment within the relevant market and are therefore well-equipped to determine whether the agreement in question is likely to have a foreclosing effect on the market. Furthermore, the test can also be applied to a situation where the brand company enters into pay for delay settlements with a number of generic companies in order to foreclose the market.

It is not suggested that the proposed test, and more precisely the evidentiary burden of the European Commission to quantify the value considerations from the brand company to the generic company, is straightforward to satisfy. Quantifying the cost of litigation is only one aspect. Although it might

sound more challenging to put a “price tag” on an exclusive licence that is granted as part of a side deal for other services rendered in relation to drug distribution or the provision of back-up manufacturing capacity, its complexity has been downplayed given that these services are routinely sold in a broad market.<sup>150</sup> The European Commission should therefore have a number of reference points in the market. The alternative to the quantification of the value transfer would be an investigation into the validity of the underlying patent, which is not only more onerous but also more problematic for the European Commission. This is due to the fact that the assessment of patent validity by a competition authority leads to the “second-guessing” of patent authorities and the potential judgment of a patent court. Such a judgment is not, however, a quantitative exercise but rather a subjective value judgment with regard to the relevant prior art of the patent and its “non-obviousness” or “inventive step”. Judges in one jurisdiction might hand down a judgment that contradicts judgments regarding the same patent in another jurisdiction. Thus, it is regarded as a lot more sensible and much less onerous for the competition authority to undertake the quantitative exercise to evaluate the consideration flowing from the brand company to the generic company than delving into the subjective assessment of patent validity. Ultimately, this approach therefore enhances legal certainty.

### **3. Abuse of a dominant position**

Pay for delay settlements have already been scrutinised under Art. 101 TFEU under the previous section. It has been shown in the theory of harm chapter that pay for delay settlements are used as a vehicle to foreclose the relevant market by paying off potential generic entrants.<sup>151</sup> In return for this value transfer, the potential generic entrant agrees not to enter the market before a certain date that has been stipulated in the settlement agreement.

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<sup>150</sup> Hovenkamp (n 118) 27, 28.

<sup>151</sup> See chapter III.

However, a situation could also be envisaged where pay for delay settlements are used in a broader “product lifecycle management”<sup>152</sup> strategy of the brand company. If a brand company enters into a pay for delay settlement with a potential generic entrant in order to facilitate unilateral conduct, one should consider antitrust scrutiny following under Art. 102 TFEU. This option could also be of strategic advantage. In an investigation against a brand company regarding the alleged abuse of its dominant position, the European Commission is more likely to receive cooperation from the generic company that entered into the pay for delay settlement, as only the brand company is subject to the investigation. This is also unlikely to be an undue prioritisation of the enforcement, as the investigated conduct is based on unilateral conduct that has been facilitated by the agreement between the brand company and the generic company. The predominant anticompetitive potential is therefore likely to stem from the brand company’s unilateral conduct.

Due to the different focal point, an investigation of a brand company’s abuse of dominance should therefore be seen as an alternative enforcement strategy against pay for delay settlements rather than a complementary approach to the analysis of pay for delay settlements under Art. 101 TFEU.

An example of this broader type of unilateral conduct by the brand company, which goes beyond the competitive practice of “product lifecycle management”, can be found under the “second” abuse in *AstraZeneca*, concerning the deregistration of a market authorisation in order to avoid generic entry and to facilitate AstraZeneca’s product switch to a second generation version of its brand drug Losec.

This section argues that an adapted version of this conduct, in which the deregistration of the marketing authorisation is replaced by a pay for delay settlement, can lead to the same anticompetitive result and therefore to an abuse

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<sup>152</sup> Product lifecycle management is the business activity of managing a company’s products across their lifecycle, from the very first idea of a product all the way through until it’s retired and disposed of. The main objectives are the increase of product revenue, the reduction of product related costs, and the maximisation of the product portfolio’s value for customers and shareholders. John Stark, *Product lifecycle management: 21st century paradigm for product realisation* (2<sup>nd</sup> edn, Springer, London 2011) 1.

of the brand company's dominant position. For this purpose, the "second" abuse in *AstraZeneca* is explained first, before the scenario is adapted to pay for delay settlements.

### 3.1. The second *AstraZeneca* abuse – deregistration of market authorisations

The European Commission's finding of abuse in relation to the selective deregistration of market authorisations for AstraZeneca's brand drug Losec was based on AstraZeneca's so-called "Losec Post-Patent Strategy" which consisted of three elements: (1) the extension of the Losec product line by Losec MUPS, which is Losec in a tablet form instead of a capsule,<sup>153</sup> (2) the raising of technical and legal barriers to entry designed to delay generic entry which was accomplished through the deregistration of the marketing authorisations for Losec capsules in several Member States; and (3) the introduction of a new generation product called esomeprazole, which was supposed to have significant clinical benefits compared to omeprazole, the active pharmaceutical ingredient in Losec.<sup>154</sup>

The importance of getting the timing right for the entry of a follow-on brand drug such as Losec MUPS is highlighted by a statement made by a brand company during the European Commission's sector inquiry. The company stated that:

*"[t]he launch of [our second generation product] is a challenge, not experienced until now, as generics firms, [...] press onto the market with all force and as we have to fear the loss of our patent [...]. This means each patient that is not switched quickly enough to [our second generation product] is forever lost to the generics. Once the patient is switched to [our second generation product] the physician does not have to, cannot and will not switch him to a generic, and what is more important: the pharmacist cannot substitute!!"*<sup>155</sup>

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<sup>153</sup> It needs to be kept in mind that the extension of the product line by itself does not constitute an abuse as 'an undertaking, even in a dominant position, [can employ] a strategy whose object it is to minimise erosion of its sales and to enable it to deal with competition from generic products is legitimate and is part of the normal competitive process' Case T-321/05 *AstraZeneca v European Commission* [2010] ECR 00 para. 804.

<sup>154</sup> For the purpose of the finding of abuse only the first two points are relevant. *Ibid.* para. 803.

<sup>155</sup> European Commission (n 1) 360.

If a generic version of the original brand drug arrives on the market before the brand company has switched to a follow-on version of the brand drug, the brand company not only loses sales volumes but also has to deal with significantly lower prices for its original brand drug.<sup>156</sup>

In order to switch as many patients as possible from Losec to Losec MUPS before generic entry, AstraZeneca raised barriers to entry by means of creating regulatory obstacles that prevented generic companies from obtaining marketing authorisations for generic versions of Losec.<sup>157</sup> These regulatory obstacles were created through the selective deregistration of AstraZeneca's marketing authorisation for Losec. According to the legal framework at the time, an abridged drug application for the generic drug, upon which the generic company could rely on the clinical trials and the necessary scientific literature,<sup>158</sup> was only available if the marketing authorisation for the brand drug was in force on the date on which the generic abridged drug application was filed.<sup>159</sup> With the withdrawal of the marketing authorisation, AstraZeneca had prevented generic companies from using the abridged application procedure and had therefore delayed generic entry and increased the generic companies' costs to overcome this barrier to market entry.<sup>160</sup> Based on this conduct the European Commission found that:

*'the requests for deregistration of capsules in [...] combination with the tablet/capsule switch (i.e. the launch of Losec MUPS tablets and the withdrawal from the market of Losec capsules), as part of its LPPS Strategy with a view to preventing, or at least delaying, generic market entry [resulted in an abuse of AstraZeneca's dominant position]'*.<sup>161</sup>

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<sup>156</sup> Ibid. 356.

<sup>157</sup> Instant switching from one brand drug to another is not likely to happen due to described switching inertia of prescribing doctors that has been discussed in detail in relation to market definition in chapter II sec. 5.1.1.1.

<sup>158</sup> For a detailed explanation of the abridged application procedure see Appendix sec. 2.3.

<sup>159</sup> Case T-321/05 *AstraZeneca v European Commission* (n 153) para. 828.

<sup>160</sup> Ibid. para. 829. Generic companies could still enter the market but were unable to rely on AstraZeneca's clinical data.

<sup>161</sup> *AstraZeneca* (Case COMP/A. 37.507/F3) Commission Decision 2006/857/EC, [2005] OJ L 332 para. 860. This finding was upheld by the General Court Case T-321/05 *AstraZeneca v European Commission* (n 153) para. 671-696 and by the ECJ Case C-457/10 P *AstraZeneca v European*

The abuse is therefore not to be found in the extension of the product line but in the delay of generic competition into the market, which allowed the brand company to introduce a follow-on brand drug into the same market and, thereafter, attempt to switch as many patients as possible to the new follow-on brand drug without fear of generic competition. In doing so, the brand company would be able to switch patients to its new – and still patent protected – follow-on version of the brand drug. If successful, the brand drug would not face significant competitive pressure from generic entrants as these could only enter with a generic version of the brand drug but not for the follow-on brand drug, which is effectively replacing the brand drug on the same market.

Finally, it should be noted that this kind of abuse, based on the deregistration of market authorisations, is no longer feasible due to the replacement of Council Directive 2001/83/EC by Directive 2004/27/EC.<sup>162</sup> Since this change in secondary legislation, the deregistration of a marketing authorisation can no longer prevent a generic applicant from relying on the necessary clinical trial data of the brand company. It is now sufficient that the brand drug has received marketing authorisation for its drug in an EU Member State at some point in the past, meaning the authorisation no longer has to be active at the time of the generic application.<sup>163</sup>

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Commission (ECJ, 6 December 2012) para. 129-141 holding that ‘the deregistration of [Losec’s marketing authorisation] [...] by which AstraZeneca intended [...] to hinder the introduction of generic products [...] does not come within the scope of competition on the merits.’ at [130].

<sup>162</sup> Directive E 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use .

<sup>163</sup> Ibid. ‘if the reference medicinal product was not authorised in the Member State in which the application for the generic medicinal product is submitted [...] the applicant shall indicate in the application form the name of the Member State in which the reference medicinal product **is or has been authorised**. At the request of the competent authority of the Member State in which the application is submitted, the competent authority of the other Member State shall transmit within a period of one month, a confirmation that the reference medicinal product is or has been authorised together with the full composition of the reference product and if necessary other relevant documentation.’ (emphasis added) at Art.10(1).

### 3.2. Pay for delay settlements – The delay of generic entry in a broader context

A pay for delay settlement could replace the closed loophole of deregistration in the product switching scenario. As has been discussed in Chapter III, pay for delay settlements in the European context do not necessarily provide the brand company with the opportunity to foreclose the market by paying off a single generic competitor. The foreclosure of the relevant market depends heavily on the competitive structure of the market and the number of generic companies that are capable of entering the market and of posing a viable threat to the brand company's monopoly profits. Nonetheless, the brand company could attempt to delay the most viable and imminent entrant via a pay for delay settlement, in order to gain sufficient time to introduce the follow-on brand drug into the same market as the brand drug. As described in the section above, it is vital for the brand company to introduce the follow-on brand drug on the market before generic competition for the original brand drug arises.<sup>164</sup> The introduction of a follow-on brand drug also does not constitute an abuse itself, as it is part of the normal competitive process to mitigate the erosion of sales.<sup>165</sup> The pay for delay settlement, however, ensures that the brand company can introduce the follow-on brand drug on the market without the fear of generic competition and can attempt to switch as many patients as possible from the original brand drug to the new follow-on brand drug. With generic competition present in the market, the switch of patients would be less likely to be successful on a large-scale as patients are more likely to be switched to the generic version of the original brand drug than to the follow-on brand drug due to the likely significant price difference. A pay for delay settlement could therefore be used by a brand company in the same manner as the deregistration of marketing authorisations in *AstraZeneca*, meaning such agreements should therefore also be regarded as not falling within the scope of competition on the merits given that it delays the introduction of generic products.<sup>166</sup>

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<sup>164</sup> European Commission (n 1) 360.

<sup>165</sup> Case T-321/05 *AstraZeneca v European Commission* (n 153) para. 804.

<sup>166</sup> See Case C-457/10 P *AstraZeneca v European Commission* (n 161) para. 130.

The brand company could legitimately attempt to switch patients to the follow-on drug by introducing the follow-on brand drug into the market after the brand company's data exclusivity has elapsed but before the 2-year period of market exclusivity has expired.<sup>167</sup> The brand company might argue that the switch at this point in time could lead to the cannibalisation of profits from the original brand drug that is still patent protected. But it should also be noted that the follow-on brand drug is likely to still be under data exclusivity and is thus shielded from generic competition for a longer period. In contrast to this legitimate business practice, the brand company delays generic entry by paying off the generic company to a point in time after the expiry of market exclusivity. This means that, under normal circumstances, the paid-off generic company could have had the potential to enter the market. This could lead to the minimisation of the aforementioned profit cannibalisation and to a successful product switch at a point in time when the generic company could have already exerted competitive pressure on the original brand drug, which would directly benefit consumers. Consumers would have been more likely to switch to the cheaper generic version of the original brand drug than to the follow-on brand drug. Therefore, the conduct in question should be regarded as an abuse of the brand company's dominant position.

What remains to be discussed is whether the brand company could argue that the conduct is objectively justified. The brand company could rely on the exclusionary nature of the patent, arguing that it should also be allowed to defend its patent by means of patent infringement litigation when the litigation is concluded by a settlement. A similar argument was put forward in *Microsoft*.<sup>168</sup> However, Microsoft's plea that it should be allowed to refuse to grant access to its technology to third parties based on the fact that the technology was patent protected was rejected by the General Court. The Court held that this would lead to the conclusion

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<sup>167</sup> Every brand drug that has been approved after 30 October 2005 receives 8 years of data exclusivity (where a generic company cannot rely on the brand company's clinical data), 2 years of market exclusivity (where the generic company can produce the drug but is not allowed to market it) with a possible extension of a further year (so-called 8+2+1 formula). For more details see Appendix sec. 2.3.

<sup>168</sup> *Case T-201/04 Microsoft v. Commission* [2007] ECR II-3601.



that refusal to licence an intellectual property right could never constitute an abuse, which would contradict the ECJ's judgments in *Magill* and *IMS Health*.<sup>169</sup> In a similar vein, it could be argued that it should not be permissible to shield any patent enforcement from antitrust scrutiny because of the exclusionary nature of the patent.<sup>170</sup> In addition, the conduct should not be objectively justifiable by arguing that incentives to innovate would be reduced. Contrary to Microsoft, which dealt with the refusal to licence an intellectual property right, the brand company is not curtailed in putting an innovative product to the market and is not forced into providing a generic company with a licence. Instead, the company is prevented from shielding the market from generic competition which allows the brand company to make the transition from an original brand drug to a follow-on brand drug without any competitive constraint from generic companies. The brand company should also not be able to argue that the pay for delay settlement which facilitates the product switch would realise efficiencies to the benefit of the consumers, as the purpose of a pay for delay settlement is to keep cheaper generic alternatives to the original brand drug out of the market.

Following these remarks, it can be concluded that pay for delay settlements could be used as a means to an end for the brand company to succeed with a broader unilateral conduct, which would justify an investigation under Art. 102 TFEU.

#### 4. Conclusion

The discussion of pay for delay settlements as agreements between competitors has shown that the EU courts' previous case law regarding trademark delimitation agreements and no-challenge clauses are not applicable to this scenario. It has

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<sup>169</sup> Ibid. para.690 In *Magill* and *IMS Health* the ECJ stated that refusal to licence can constitute an abuse of a dominant position.

<sup>170</sup> This would circumvent antitrust scrutiny of potential anticompetitive conduct such as vexatious patent litigation such as the European Commission's investigation against Rambus for their "patent ambush" strategy which has been concluded by a commitment decision *RAMBUS (Case COMP/38.636)* Commission decision [2010] OJ C30/17; or the recent investigations against Samsung in relation to standard-essential patents, European Commission, *Antitrust: Commission sends Statement of Objections to Samsung on potential misuse of mobile phone standard-essential patents* (Brussels, 21 December 2012) < [http://europa.eu/rapid/press-release\\_IP-12-1448\\_en.htm](http://europa.eu/rapid/press-release_IP-12-1448_en.htm)>.

therefore been necessary to develop a novel test for pay for delay settlements which, in essence, consists of a structured effects-based analysis in which the actual or potential anticompetitive effects of pay for delay settlements are inferred through the size of the value transfer from the brand company to the generic company. To base an effects-based analysis on limited evidence is not unheard of, as has been shown by reference to the EU courts' case law in relation to the information exchange between competitors. The key advantage of the proposed test is the fact that it evades the need for a subjective assessment of patent validity by the competition authority. It is rather founded on a cost-based analysis by which the competition authority has to quantify the costs and services rendered that are included in the relevant pay for delay settlement. The European Commission should be a lot more at ease to employ such a cost-based analysis. At the same time, care was taken to ensure that the proposed test was not over-inclusive, recognising the need for general patent settlements.

The analysis of pay for delay settlements as part of a broader unilateral strategy has shown that the settlement can be used to delay generic entry long enough, in order to implement such a broader strategy that might be aimed at extending the brand company's monopoly profits. The discussed example shows that legitimate competitive business practice can become anticompetitive if the brand company employs a pay for delay settlement in order to ensure the success of the business practice by sheltering it from generic competition. Such conduct should not fall within the scope of competition on the merits and should not be objectively justified.

Having discussed pay for delay settlements within the remit of Art. 101 TFEU and Art. 102 TFEU, the following final substantive chapter of this thesis puts early entry agreements under the same kind of scrutiny based on European competition law.

## V. EARLY ENTRY AGREEMENTS

### 1. Introduction

An early entry agreement is an agreement that is reached between a brand company and a generic company, prior to the expiry of the relevant patents, that relates to the brand drug. Having finalised the agreement, the generic company is allowed to enter the market early. In return for this permitted early entry, the generic company has to commit to a number of exclusivity clauses as part of its agreement with the brand company. These clauses can impose a variety of restrictions on the generic company, such as exclusive sourcing agreements, single branding agreements and exclusive distribution agreements.<sup>1</sup> The key issue that should trigger antitrust scrutiny is the time frame in which these agreements take place. As this thesis has mentioned previously,<sup>2</sup> at least half of the agreements identified in the European Commission's pharmaceutical sector inquiry were entered into by the parties one year prior to the loss of exclusivity of the brand company's patent. On average, the agreements exceeded the loss of this exclusivity by two years; however, the most extreme case saw the exclusivity exceeded by more than 14 years. Indeed, it is this fact – ie that the exclusive nature of the agreement between the brand company and the early generic entrant exceeds the loss of patent protection – which raises particular concerns for antitrust.

Based on the above-developed theory of harm,<sup>3</sup> the antitrust concern should stem from the brand company's ability to control the price of the generic drug sold by the first generic entrant beyond the life of the patent. The brand company could therefore prevent or delay a significant generic price drop shortly after patent expiry, thereby distorting the competitive process and harming consumers. This strategic control is only possible if the generic first-mover advantage is exploited and subsequent entry is foreclosed or delayed after patent expiry. The focus of this chapter is therefore on: the restrictions that are imposed on the early generic entrant by the brand company through the early entry

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<sup>1</sup> For a detailed discussion of the composition of early entry agreements see chapter III sec. 3.

<sup>2</sup> See chapter III section 3.

<sup>3</sup> For the detailed analysis of the theory of harm see Chapter III.

agreement; the potential foreclosure or the delayed entry of subsequent generic entrants; and the competing brand companies that also want to enter the generic market by means of an early entry agreement.

This chapter addresses the anticompetitive potential of early entry agreements prior to patent expiry as well as post-patent expiry. Just as in the analysis of pay for delay settlements in the previous chapter, the discussion of early entry agreements also focuses on: (1) agreements between competitors within the remit of Art. 101 TFEU, and (2) the potential abuse of the brand company's dominant position following Art. 102 of the Treaty on the Functioning of the European Union (TFEU).

In section 2, the discussion focuses predominantly on the applicability of the relevant block exemptions to early entry agreements. This analysis highlights the general procompetitive nature of early entry agreements prior to patent expiry, but also hints at the anticompetitive potential of these agreements post-patent expiry. Continuing under the assumption that the brand company is in a dominant position, the analysis in section 3 of this chapter shows that the brand company runs the risk of abusing its dominant position by means of anticompetitive foreclosure or by delaying the entry of subsequent generic companies and competing brand companies. In doing so, the brand company is able to keep the price of the generic drug above the competitive level post-patent expiry which, therefore, harms the consumer.

## **2. Agreement between competitors**

The generic company is predominantly in a vertical relationship with the brand company, because it either purchases the drug from the brand company and resells it following the generic packaging, or it purchases all the necessary requirements from the brand company in order to manufacture the generic version of the brand drug. However, the generic company could also be regarded – to some extent – as a competitor to the brand company, as it sells the perfect substitute to the brand drug on the same relevant market. Determining the relationship between the two

parties also has a significant impact on the application of Art. 101 TFEU to this scenario. Depending on the details of the actual terms, the agreement could fall into the remit of two different block exemptions – namely the Vertical Block Exemption Regulation (VBER),<sup>4</sup> and the Technology Transfer Block Exemption Regulation (TTBER).<sup>5</sup>

The TTBER applies only to agreements for the production of a contract product.<sup>6</sup> The patent licence that is incorporated into the technology transfer agreement must therefore relate to the production of the contract product.<sup>7</sup> In contrast, licences in agreements that are predominantly aimed at the reselling and distribution of a product – rather than its production – have to be evaluated under VBER instead of the TTBER.<sup>8</sup> The block exemptions might potentially have different market share thresholds that determine their applicability and which may lead to different outcomes in relation to the scrutiny of early entry agreements under Art. 101 TFEU. Thus this discussion requires setting up two different scenarios of early entry agreements, as it is necessary to determine the application of either the VBER or the TTBER depending on the terms of the agreement.

**Scenario 1** (the ‘rebranding scenario’) concerns an early entry agreement in which the generic company is not producing the generic version of the brand drug itself, but rather functions as a licensed distributor of the brand drug which the generic company has relabelled.

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<sup>4</sup> Commission Regulation (EU) No 330/2010 on the application of Article 101(3) of the Treaty on the Functioning of the European Union to categories of vertical agreements and concerted practices (2010) OJ L 102/1.

<sup>5</sup> Commission Regulation (EC) No 772/2004 on the application of Article 81(3) of the Treaty to categories of technology transfer agreements (2004) OJ L 123.

<sup>6</sup> Ibid. Art 2.1 (the term contract product refers to the product that is produced based on the technology transfer agreement)

<sup>7</sup> Lars Kjolbe and Luc Peepkorn, ‘The New Technology Transfer Block Exemption Regulation and Guidelines’ in Claus-Dieter Ehlermann and Isabela Atanasiu (eds), *European competition law annual 2005: The interaction between competition law and intellectual property law* (Hart, Oxford 2007) 165.

<sup>8</sup> Steven D Anderman, *EU competition law and intellectual property rights: The regulation of innovation* (2<sup>nd</sup> edn., Oxford University Press, Oxford, 2011) p.258.

**Scenario 2** (the ‘manufacturing scenario’) concerns an early entry agreement in which the generic company receives a licence from the brand company that allows the generic company to manufacture and market the actual generic version itself.

In both scenarios, the discussion focuses on the applicability of the relevant block exemption, their necessary prerequisites, and the European Commission’s Guidance on the potential application of Art. 101(3) TFEU if the block exemption should not be applicable. This section does not therefore seek to answer the question of whether early entry agreements would be covered by Art. 101, as this is a highly fact-specific question. It instead showcases the need for a robust market definition in order to accurately determine the market shares of the parties involved, as well as the potential procompetitive effects that arise from early entry agreements. At the same time, the discussion of the two scenarios outside the safe harbours of the respective block exemptions alludes to the anticompetitive potential that arises when the brand company has market power. The “grey area” for the conduct of companies with a market share outside the block exemption but shy of dominance is not addressed in detail. In these cases, Art. 101 TFEU would generally be applicable, but the information provided by the European Commission in its pharmaceutical sector inquiry is not sufficiently detailed to determine the exact nature of the agreements. The analysis would be particularly problematic in relation to Art. 101(3) TFEU. Instead, the sections on early entry agreements outside the respective block exemption regulations highlight, in general terms, the European Commission’s stance towards these initially procompetitive agreements once entered into by parties with a degree of market power. This discussion then builds up to an examination of the brand company’s abuse of its dominant position in section 3, where the anticompetitive potential is discussed in detail.

## 2.1. Scenario 1 (the rebranding scenario)

In the rebranding scenario, the generic company does not actually produce the generic version of the drug but instead enters into an exclusive distribution agreement with the brand company prior to patent expiry. In its pharmaceutical sector inquiry, the European Commission identified a large number of cases which constituted a combination of supply and distribution agreements, where the brand company supplied the generic company with the drug for distribution.<sup>9</sup> In most cases, the brand company reserved the right to sell the drug itself within the territory concerned.<sup>10</sup>

### 2.1.1. Applicability of the VBER

In this scenario, the generic company does not manufacture the drug itself, which makes the TTBER inapplicable in this situation. The TTBER only covers patent licences that are granted in relation to the production of a contract product, which would be the drug in question.<sup>11</sup> Instead, the VBER can potentially become applicable because the generic company acts as a distributor for the brand company on the downstream market and does not manufacture the drug. The fact that the brand company is also selling the drug on the same market, thereby potentially acting as a competitor to the generic company, does not necessarily render the VBER inapplicable. Despite the requirement for the concerned undertakings to be active on the separate upstream and downstream markets, the VBER entails an exception for competing undertakings. According to the Regulation, agreements between competing undertakings can nonetheless be covered if the manufacturer is a supplier and a distributor *but* the buyer is only a distributor and not a manufacturer at the same time.<sup>12</sup>

This being the case, the VBER would be applicable to early entry agreements (in the rebranding scenario) as long as the market share of neither the brand

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<sup>9</sup> European Commission, *Pharmaceutical Sector Inquiry: Final Report* (2009) <<http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/index.html>> para. 843.

<sup>10</sup> *Ibid.* para. 845.

<sup>11</sup> Kjolbe and Peeperkorn (n 7) 165.

<sup>12</sup> *Commission Regulation (EU) No 330/2010* (n 4). Art. 2(4).

company nor the generic company exceeds 30 per cent and the agreement does not include any of the hard-core restrictions in Article 4 of the block exemption. Indeed, the majority of undertakings questioned during the pharmaceutical sector inquiry submitted that their market share fell below this threshold, which seems to suggest that the majority of these early entry agreements are likely to be block exempted.<sup>13</sup> However, this calculation of market share is dependent on the definition of the relevant market, which is hugely contentious in the pharmaceutical sector and can vary significantly, as shown above.<sup>14</sup> If a single drug is regarded as constituting the relevant market, then the brand company is likely to exceed the market share threshold and the generic company has, by definition, no market share at the point of entry, given that the generic company is only about to enter the market. The applicability of the VBER is only possible if the market definition is wider, taking different pharmaceutical molecules into consideration that can potentially also be used to treat the same medical condition. In this case, the brand company is likely to have a smaller market share and the generic company could have a proportion of the market share despite not having entered the market of the drug that is covered by the early entry agreement.

An additional question that arises is the VBER's applicability in light of the intellectual property rights on which the early entry agreement is based. According to the European Commission's guidelines on vertical restraints,<sup>15</sup> the VBER applies to vertical agreements containing intellectual property right provisions where the following conditions are satisfied:

- (a) The IPR provisions must be part of a vertical agreement, that is, an agreement with conditions under which the parties may purchase, sell or resell certain goods or services;
- (b) The IPRs must be assigned to, or licensed for use by, the buyer;
- (c) The IPR provisions must not constitute the primary object of the agreement;

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<sup>13</sup> European Commission (n 9) para. 812.

<sup>14</sup> See chapter II section 5 for the general discussion of the market definition in AstraZeneca and the problems that arise once the general principles of that market definition are applied to a different market such as the one for antiepileptic drugs.

<sup>15</sup> European Commission, *Guidelines on Vertical Restraints* [2010] OJ C 130/01 para 31.



- (d) The IPR provisions must be directly related to the use, sale or resale of goods or services by the buyer or its customers;
- (e) The IPR provisions, in relation to the contract goods or services, must not contain restrictions of competition having the same object as vertical restraints which are not exempted under the Block Exemption Regulation.<sup>16</sup>

Furthermore, the European Commission states that these five conditions ensure that the VBER applies to vertical agreements where the use, sale or resale of goods or services can be performed more effectively because intellectual property rights are assigned to or licensed for use by the buyer. This means that restrictions concerning the assignment or use of intellectual property rights are covered by the Regulation so long as the main object of the agreement is the purchase or distribution of goods or services.<sup>17</sup>

In the case of early entry agreements, the underlying patent is not the primary object of the agreement. It is rather ancillary to the agreement, as the generic company could not otherwise enter the relevant market and distribute the generic version of the brand drug prior to patent expiry. The VBER should therefore be generally applicable to early entry agreements in the rebranding scenario.

An early entry agreement is thus likely to be block exempted from Art. 101 TFEU, provided it does not contain any hard-core restrictions listed under Art. 4 of the VBER. These include minimum resale price maintenance,<sup>18</sup> in addition to territorial resale restrictions in terms of passive sales.<sup>19</sup>

### **2.1.2. Early entry agreements outside the safe harbour of the VBER**

Once one of the parties to an early entry agreement does not meet the market share threshold of 30 per cent in the relevant market, the agreement in question

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<sup>16</sup> Ibid.

<sup>17</sup> Ibid. para 32.

<sup>18</sup> Maximum resale price maintenance and the setting of a recommended resale price is expressly excluded from the hard-core restrictions in Art. 4 (a) of the VBER.

<sup>19</sup> The restriction of active sales is again excluded from the hard-core restrictions following Art. 4 (b) (i) of the VBER.

becomes subject to a full competition analysis and the potential individual exception following Art. 101(3) TFEU. The guidelines assist in the individual assessment of vertical agreements outside the block exemption but, importantly, the established principles set out cannot be applied mechanically and must rather be applied on a case-by-case basis taking into consideration the specific facts of the case at hand.<sup>20</sup> Nonetheless, it should be possible to derive a few general principles that should be applicable to early entry agreements.

Early entry agreements in the rebranding scenario consist predominantly of single branding agreements<sup>21</sup> combined with exclusive sourcing agreements.<sup>22</sup> Such agreements generally bear the possibility of anticompetitive foreclosure of the market for competing potential suppliers, which could ultimately have a detrimental impact on inter- and intra-brand competition for the consumer.<sup>23</sup> The extent, or rather the likelihood, of this theory of harm materialising depends on a number of factors, including the competitive market structure in terms of the position of the supplier<sup>24</sup> and the competitors<sup>25</sup> the level of consumer demand, the

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<sup>20</sup> European Commission, *Guidelines on Vertical Restraints* (n 15) Recital 3 of the preamble.

<sup>21</sup> Single branding agreements restrict the generic company in its sales and distribution activities (e.g. territorial restrictions, or the prohibition to sell products from competing brand companies)

<sup>22</sup> This clause obliges the generic entrant to purchase all or at least most of the necessary requirements from the brand company or a designated supplier.

<sup>23</sup> European Commission, *Guidelines on Vertical Restraints* (n 15) para. 130. For a discussion of anticompetitive foreclosure through vertical restraints see Patrick Rey and Thibaud Vergé, *The economics of vertical restraints*. Conference paper at the conference on Advances in the Economics of Competition Law, (Rome, Italy, June 2005) <<http://www.economics.soton.ac.uk/staff/verge/Verticals.pdf>> 33-41; Francine Lafontaine and Margaret Slade, *Exclusive Contracts and Vertical Restraints: Empirical Evidence and Public Policy* Conference paper at the conference on Advances in the Economics of Competition Law, (Rome, Italy, June 2005) <[http://pages.stern.nyu.edu/~rslee/teaching/io/papers.vertical/Lafontaine%20Slade%20\(2007%20handbook%20antitrust\)%20%20Exclusive%20Contracts%20and%20Vertical%20Restraints.pdf](http://pages.stern.nyu.edu/~rslee/teaching/io/papers.vertical/Lafontaine%20Slade%20(2007%20handbook%20antitrust)%20%20Exclusive%20Contracts%20and%20Vertical%20Restraints.pdf)> 8-10. Generally, anticompetitive foreclosure in vertical restraints is based on the more general strategy of raising rivals' cost as developed by Steven C Salop and David Scheffman, 'Raising Rivals' Costs' (1983) 73 *The American Economic Review* 267; Thomas G Krattenmaker and Steven C Salop, 'Anticompetitive Exclusion: Raising Rivals' Costs to Achieve Power over (1986) 96 *The Yale Law Journal* 209; Steven C Salop and David Scheffman, 'Cost-Raising Strategies' (1987) 19 *The Journal of Industrial Economics* 19.

<sup>24</sup> European Commission, *Guidelines on Vertical Restraints* para. 132.

<sup>25</sup> *Ibid.* para 134.

market coverage of the single branding agreement,<sup>26</sup> barriers to entry,<sup>27</sup> and finally the duration of the agreement.<sup>28</sup>

As a general rule, it can be said that the potential for anticompetitive foreclosure increases with the level of market power of the undertakings concerned.<sup>29</sup> The higher the market shares are, the higher the tied market share is likely to be, which translates into a higher degree of market coverage for the single branding agreement. *'Single branding obligations are more likely to result in anti-competitive foreclosure when entered into by dominant companies.'*<sup>30</sup>

If it were to be established that the early entry agreement in question would lead to an anticompetitive foreclosure of the relevant market, it would be necessary to determine whether any pro-competitive effects are likely to outweigh the foreclosure effects.

The main line of argument for the objective justification of exclusivity agreements between the supplier and the distributor is based on: the distributor's incentives for investment, the free-riding problem that might occur when other competitors enter the market and the issue of "hold-up".<sup>31</sup> It has been argued that the distributor would only be willing to invest in a distribution network or the pre- and post-sale services – such as promotional expenses and staff-training – in return for exclusivity, as these costs are often sunk.<sup>32</sup> Without such exclusivity, other competitors might enter the market and "free-ride" on the pre- and post-sale services, thereby enabling them to offer the product at a lower price because they

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<sup>26</sup> Ibid. para 133.

<sup>27</sup> Ibid. para 136.

<sup>28</sup> Ibid. para 133. *'Single branding obligations shorter than one year entered into by non-dominant companies are generally not considered to give rise to appreciable anti-competitive effects or net negative effects. Single branding obligations between one and five years entered into by non-dominant companies usually require a proper balancing of pro- and anti- competitive effects, while single branding obligations exceeding five years are for most types of investments not considered necessary to achieve the claimed efficiencies or the efficiencies are not sufficient to outweigh their foreclosure effect.'*

<sup>29</sup> Simon Bishop and Mike Walker, *The economics of EC competition law: Concepts, application and measurement* (University Sweet & Maxwell, London 2010). 5-039 An anticompetitive potential of a vertical restraint arises when the restraint reduces competition on a horizontal level, which in turn depends on the degree of market power of the relevant undertakings.

<sup>30</sup> European Commission, *Guidelines on Vertical Restraints* (n 15) para. 133.

<sup>31</sup> Rey and Vergé (n 23) 23.

<sup>32</sup> Lafontaine and Slade (n 23) 7.

did not incur the service cost in the first place.<sup>33</sup> Where the distributor is likely to incur significant start-up costs in order to develop a new market, territorial exclusivity – including the restriction of passive sales for a period of up to two years – can be justified.<sup>34</sup> The hold-up problem describes the situation in which the distributor needs to be incentivised in order to set up a distribution network or any other infrastructure that is specific to the distribution agreement.<sup>35</sup> However, the hold-up issue should be negligible in the case of early entry agreements, as the distribution network developed by the early generic entrant is one of the key considerations for the brand company to actually enter into such an agreement.<sup>36</sup> Additionally, the set-up costs of the early generic entrant should be comparatively low in the rebranding scenario because it does not have to produce the generic drug in the first place. The early generic entrant simply has to distribute the drug provided by the brand company using its already established distribution network.

In the case of early entry agreements, however, the exclusive nature of the agreement can instead be justified by the existence of the patent that protects the brand drug. Prior to patent expiry, the brand company could technically try to exclude every generic company from the market. It should therefore be acceptable for the brand company to restrict the distribution of the generic drug by the generic company. However, as soon as the drug has lost its patent protection, the situation needs to be re-evaluated. At this point, any objective justification of the exclusivity based on the need to incentivise the generic company should be carefully considered. Despite the fact that the exclusivity prior to patent expiry is based on the patent protection of the brand drug, the generic company also benefits from this exclusivity period as it means it need not fear any generic competitor. This enables the generic company to establish itself on the market and to recoup its investment in the launch of the generic drug, as well as eradicating any free-riding problem.

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<sup>33</sup> Lester G Telser, 'Why Should Manufacturers Want Fair Trade?' (1960) 3 *Journal of Law and Economics* 86, 91.

<sup>34</sup> European Commission, *Guidelines on Vertical Restraints* (n 15) para. 61.

<sup>35</sup> *Ibid.* para. 107 (d).

<sup>36</sup> European Commission (n 9) para 729.

Thus, once the patent has expired, it should be – at the very least – exceedingly difficult to objectively justify any exclusivity contained in the early entry agreement.

### **2.1.3. Early entry agreements in the light of the VBER**

Early entry agreements that fall within a safe harbour of the VBER are likely to be block exempted as they are unlikely to include any hard-core restrictions. Even if the agreement were to include a hard-core restriction such as the restriction of passive sales, the agreement should be individually exempted under Art. 101(3), due to the patent protected nature of the brand drug. The agreement does, after all, provide a generic version of the brand drug prior to patent expiry which is beneficial to consumer welfare.

However, the situation changes once the brand drug comes off patent. If the early entry agreement is stipulated for a period that exceeds the patent life, and if the parties exceed the market share threshold, the agreement is unlikely to satisfy Art. 101(3) TFEU, as any objective justification for such exclusivity should be rejected.

## **2.2. Scenario 2 (the manufacturing scenario)**

In contrast to the rebranding scenario above, in this scenario the generic company receives a patent licence from the brand company that allows the generic company to manufacture and sell the drug.<sup>37</sup> Under these circumstances, the generic company is required to produce a contract product which is based on the provided patent licence, thereby leading to the potential applicability of the TTBER.

### **2.2.1. Applicability of the TTBER**

For the TTBER to become applicable, the parties to the agreement in question must also satisfy a market share threshold. However, the determination of the applicable market share threshold in relation to the TTBER is more nuanced than under the VBER, as the answer to this question depends on whether the parties to the agreement are competitors or non-competitors. If the parties are regarded as

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<sup>37</sup> European Commission (n 9). para. 851.

competitors, the market share threshold is a combined 20 per cent;<sup>38</sup> if they are regarded as non-competitors, the threshold is 30 per cent each.<sup>39</sup>

*'In order to determine the competitive relationship between the parties it is necessary to examine whether the parties would have been actual or potential competitors in the absence of the agreement. If without the agreement the parties would not have been actual or potential competitors in the relevant market affected by the agreement they are deemed to be non-competitors.'*<sup>40</sup>

Based on these considerations, the parties to an early entry agreement are likely to be classified as non-competitors, as becoming a competitor by virtue of the patent licence is irrelevant to the assessment.<sup>41</sup> Without the patent licence, the generic company would not be able to produce the generic version of the patent protected brand drug. One could argue that the generic company might be able to produce the drug without the know-how conveyed by the patent licence, but even this possibility cannot be taken into consideration, as the generic company is not considered an actual or potential competitor if, in the absence of the agreement, the activity would constitute an infringement of the intellectual property rights of the other party.<sup>42</sup>

The relevant market share threshold for both parties to the agreement is therefore likely to be 30 per cent, which is similar to the situation of the rebranding scenario in relation to the VBER.

The distinction between competitors and non-competitors also has an impact on the overall assessment of the agreement in question under the TTBER, as the hard-core restrictions in relation to territorial and non-territorial restrictions differentiate between competitors and non-competitors. Furthermore, this distinction is far-reaching as it also applies to agreements outside the safe harbours,

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<sup>38</sup> Commission Regulation (EC) No 772/2004 (n 5). Art. 3 (1)

<sup>39</sup> Ibid. Art. 3 (2)

<sup>40</sup> European Commission, *Guidelines on the Application of Article 81 of the EC Treaty to Technology Transfer Agreements* [2004] OJ C 101/2 para. 27

<sup>41</sup> Kjolbe and Peeperkorn (n 7) p.8

<sup>42</sup> Commission Regulation (EC) No 772/2004 (n 5). Art. 1 (j) (ii); Kjolbe and Peeperkorn (n 7) p.9

as long as the market shares of the parties to the agreement are below the level required for dominance.<sup>43</sup>

### **Territorial restrictions**

The TTBER and its relevant Guidelines distinguish between two types of territorial restrictions – the restriction on production by means of an exclusive licence and sales restrictions.

Following the Guidelines,<sup>44</sup> an early entry agreement that provides the early generic entrant with an exclusive licence, guaranteeing that no other generic company will enter the market for the duration of the agreement, is likely to be either block exempted or individually exempted under Art. 101(3) TFEU, depending on the level of market shares. Such a licence is necessary to induce the licensee to invest in the production of the licenced technology, especially if the sunk investment is substantial,<sup>45</sup> which in turn addresses the hold-up problem. Additionally, one has to keep in mind that the licensor is sharing its patent with the generic company prior to patent expiry. The possible alternative would be the exclusion of the generic company until patent expiry, which would deprive the generic version of the brand drug from emerging prior to patent expiry.<sup>46</sup>

With regard to sales restrictions, the restriction of active sales is generally block exempted if it is within the safe harbour. Even if the agreement is outside the safe harbour but the company falls short of being dominant, the restriction of active sales is likely to be individually exempted, as the European Commission states that *'a technology owner cannot normally be expected to create direct competition with himself on the basis of his own technology.'*<sup>47</sup> Restrictions of passive sales are generally block exempted for two years from the date on which the licensee first markets the product incorporating the licenced technology, as licensees often have to commit to substantial investments on production and

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<sup>43</sup> Anderman (n 8) 259.

<sup>44</sup> European Commission, *Guidelines on the Application of Article 81* (n 40).

<sup>45</sup> *Ibid.* para 165

<sup>46</sup> Anderman (n 8) p.275.

<sup>47</sup> European Commission, *Guidelines on the Application of Article 81* (n 40) para. 172.

marketing.<sup>48</sup> If the restriction of passive sales exceeds this two year period, it is no longer block exempted and unlikely to satisfy the conditions of Art. 101(3) TFEU.<sup>49</sup> The period of two years is thus regarded as sufficient protection with regards to the start-up costs and other potential investment of the new licensee that is often sunk.<sup>50</sup>

### **Non-territorial restrictions**

Possible non-territorial restrictions in early entry agreements include non-compete obligations, no-challenge clauses and the calculation and duration of royalties.

Non-compete obligations, which prevent the licensee from using third party technologies that compete with the licenced technology, are generally exempted, so long as the parties to the agreement are within the safe harbour.<sup>51</sup> However, outside the safe harbour and especially if the licensor has significant market power, a non-compete obligation can potentially have an anticompetitive foreclosing effect if high barriers to entry impede third-party technologies from entering the market. This is the case if third-parties do not have access to the necessary production and distribution assets.<sup>52</sup>

Under the TTBER, no-challenge clauses are not black-listed but rather regarded as excluded restrictions following Art. 5 of the TTBER. These kinds of excluded restrictions do not benefit from the block exemption and can only be individually exempted following Art. 101(3) TFEU. Yet, at the same time, they do not affect the remainder of the agreement.<sup>53</sup> The licensor has a strong incentive to include such a clause in the early entry agreement, as it provides the generic company with first-hand knowledge of the patent process and potential weakness of the patent, which could lead to a potential challenge by the generic company. It is therefore likely that the licensor would completely refrain from licensing its patent in the absence of such contractual protection.

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<sup>48</sup> Ibid. para. 101.

<sup>49</sup> Ibid. para. 174.

<sup>50</sup> Kjolbe and Peepkorn (n 7) 17.

<sup>51</sup> European Commission, *Guidelines on the Application of Article 81* (n 40) para. 197.

<sup>52</sup> Ibid. para 198.

<sup>53</sup> Anderman (n 8) p.265.



The parties to the agreement are also allowed to determine the royalties which are payable by the licensee in return for the patent licence. Nonetheless, competition concerns arise when the royalty is set in a way that indirectly amounts to price fixing by restricting the licensee in its ability to determine the prices charged to third parties.<sup>54</sup> The only noted exception is the imposition of a maximum sale price or recommended sale price in a licence agreement between non-competitors.<sup>55</sup> The duration of the agreement regarding the royalties is not necessarily an indicator of sham royalties.

*‘Notwithstanding the fact that the block exemption only applies as long as the technology is valid and in force, the parties can normally agree to extend royalty obligations beyond the period of validity of the licensed intellectual property rights without falling foul of Article [101(1)]. Once these rights expire, third parties can legally exploit the technology in question and compete with the parties to the agreement. Such actual and potential competition will normally suffice to ensure that the obligation in question does not have appreciable anti-competitive effects.’<sup>56</sup>*

Thus the duration of the agreement beyond the patent life is justified on the basic notion of self-correcting markets. However, if one accepts the above-developed theory of harm,<sup>57</sup> the corrective measure of competitive constraints through subsequent generic entrants might be missing or are at least delayed. If this should be the case, the early generic entrant might pay higher royalties beyond the loss of the exclusivity of the underlying patent, ultimately leading to supra-competitive prices for the generic drug, which is to the detriment of consumer welfare.

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<sup>54</sup> Commission Regulation (EC) No 772/2004 (n 5) Art 4 (2) a.

<sup>55</sup> Kjolbe and Peepkorn (n 7) 13.

<sup>56</sup> European Commission, *Guidelines on the Application of Article 81* (n 40) para 159.

<sup>57</sup> See chapter III sec. 3.2 arguing that subsequent generic entry might be delayed because of the first-mover advantage of the early generic entrant, which is to a certain extent controlled by the brand company.

### **2.2.2. Early entry agreements in the light of the TTBER**

Having applied the TTBER in its current form, it can be deduced that early entry agreements in the manufacturing scenario are generally likely to be covered by the TTBER and the accompanying guidelines as long as the parties involved are not dominant or, at least, do not have significant market power. All restrictions potentially have pro-competitive effects as they give the generic company the incentive to invest and avoid potential free-riding problems. After all, early entry agreements deliver a generic drug to the market prior to brand drug's patent expiry, which is beneficial for the consumer.

However, once the parties have significant market power, the anticompetitive potential for foreclosure through early entry agreements might arise, similar to the discussed rebranding scenario.

### **2.3. Conclusion**

The discussion of early entry agreements under the VBER and the TTBER has shown that the single branding agreements, non-compete obligations, no-challenge clauses and sales restrictions – all of which can be included in early entry agreements – can have procompetitive features and might therefore be exempted from antitrust scrutiny. However, following the discussion of the relevant guidance, it can also be said that the European Commission is wary of these agreements once the involved parties obtain a degree of market power.

This should be even more so the case if the brand company is in a dominant position, which opens the door for an Art. 102 TFEU investigation into the potential anticompetitive effects of early entry agreements. The following section therefore discusses the brand company's potential abuse of its dominant position by controlling the early generic entrant through an early entry agreement.

### 3. Abuse of a dominant position

This section scrutinises early entry agreements in relation to Art. 102 TFEU. The emphasis here is on the potential foreclosure of the relevant market and, in addition, on the delay of entry caused by the exclusive sourcing obligations of the generic company and the single branding agreements that are incorporated into early entry agreements. As has been mentioned above, such a delay of entry is essential if the brand company is to, firstly, exploit the generic first-mover advantage with the aim of retaining control over the generic drug price post-patent expiry and, thereby, keep generic prices at a supra-competitive level.

For the purpose of this chapter, it is assumed that the brand company is in a dominant position. The fact that a dominant undertaking enters into an agreement does not contradict an analysis under Art. 102 TFEU because of the existence of unilateral conduct. Art. 101 and 102 TFEU are not mutually exclusive. Indeed, the ECJ held in *Hoffmann-La Roche*, dealing with exclusive purchasing agreements, that:

*'Article [101] does not preclude the application of Article [102] since this latter article is expressly aimed in fact at situations which clearly originate in contractual relations so that in such cases the [European] Commission is entitled, taking into account the nature of the reciprocal undertakings entered into and to the competitive position of the various contracting parties on the market or markets in which they operate to proceed on the basis of Article [101] or Article [102].'<sup>58</sup>*

Particularly in the case of early entry agreements, it is sensible to scrutinise the brand company's conduct under Art. 102 TFEU, as these agreements are based on the brand company's patent(s) - a patent is also a form of temporary legal monopoly, which is likely to impact upon the brand company's position in the market. In addition, these agreements are entered into prior to the expiry of the brand company's patent but continue beyond the date of expiry. This situation

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<sup>58</sup> Case 85/76 *Hoffmann-La Roche & Co. AG v Commission* [1979] ECR 461 para. 116.

increases the potential for the brand company to abuse its assumed dominant position post-patent expiry.

This section is structured as follows. Before turning to the legal analysis of exclusive sourcing obligations and single branding agreements as part of early entry agreements, section 3.1 discusses the brand company's special responsibility to not distort competition in light of the fact that the brand company's patent protection expires inside the duration of the early entry agreement. Section 3.2 examines the generic company's exclusive sourcing obligation prior and post-patent expiry based on the relevant decisional practice and guidance offered by the European Commission and the relevant case law. By further utilising these sources, section 3.3 examines single branding agreements and their potential for anticompetitive foreclosure of subsequent generic entrants and competing brand companies, as well as the agreement's potential for the restriction of choice of the early generic entrant. Both sections suggest that the EU Courts are likely to follow a more formalistic approach to these kinds of agreements. This approach is thereby critiqued and an argument is put forward in favour of an alternative approach consisting of an effects-based case-by-case analysis.

### **3.1. The brand company's special responsibility**

A dominant undertaking's special responsibility is a fundamental principle governing Art. 102 TFEU. Since the ECJ's judgment in *Michelin*, the EU Courts have consistently held that the dominant undertaking, irrespective of the reasons for which it has acquired such a dominant position, has the special responsibility to not impair undistorted competition on the Common Market.<sup>59</sup> In *Compagnie Maritime Belge*, the ECJ further elaborated that:

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<sup>59</sup> *Case 322/81 NV Nederlandsche Baden-Industrie Michelin v Commission* [1983] ECR 3461 para. 57.

*‘the actual scope of the special responsibility imposed on a dominant undertaking must be considered in the light of the specific circumstances of each case which show that competition has been weakened.’<sup>60</sup>*

This statement seems to suggest that the concept of the special responsibility is based on a sliding scale of sorts, placing a particular heavy responsibility towards the competitive process for undertakings in a monopolistic or quasi-monopolistic position.<sup>61</sup>

According to the recent ECJ judgment in *Post Danmark*, one factor that should be taken into consideration is whether the dominant position of the undertaking in question originates from a former legal monopoly.<sup>62</sup> This finding suggests that the special responsibility of a dominant undertaking depends, to a certain extent, on the circumstances that lead to the undertaking’s dominant position. In the case of *Post Danmark*, the undertaking held a monopoly within the market for the delivery of addressed letters prior to the liberalisation of the postal sector in Denmark.<sup>63</sup> With this case in mind, Rousseva argues that a legal monopoly conferred by the state might justify stricter antitrust scrutiny than would usually be expected. Because of the monopoly, the undertaking has enjoyed certain advantages – such as state resources, an established customer base or network effects – which, in return, makes it more difficult for entrants to become as efficient as the dominant undertaking, leading to possible adverse effects on the interests of consumers.<sup>64</sup> It is therefore the dominant position resulting from a legal monopoly that warrants an enhanced special responsibility of the undertaking to not impair undistorted competition after the sector has been liberalised.<sup>65</sup>

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<sup>60</sup> Cases C-395 and 396/96P, *Compagnie Maritime Belge and Others v. Commission* [2000] ECR I-1365 para. 114.

<sup>61</sup> Alison Jones and Brenda Sufrin, *EU competition law: Text, cases, and materials* (5<sup>th</sup> edn, Oxford University Press, Oxford 2014) 423.

<sup>62</sup> Case C-209/10 *Post Danmark A/S v Konkurrenceradet* (ECJ, 27 March 2012) para. 23.

<sup>63</sup> *Ibid.* para. 4.

<sup>64</sup> Ekaterina Rousseva and Mel Marquis, ‘Hell Freezes Over: A Climate Change for Assessing Exclusionary Conduct under Article 102 TFEU’ (2013) 4 *Journal of European Competition Law & Practice* 32, 44.

<sup>65</sup> *Ibid.* 44.

The special responsibility of a former legal monopolist post-liberalisation is not dissimilar to the situation of a patent holder post-patent expiry. As suggested above, a patent can also be regarded as a form of a legal monopoly. Although it can be challenged by competitors, the patent nonetheless confers a right on the holder of a valid patent to exclude any competitor that wants to make, sell or use the patented invention for a fixed period.<sup>66</sup> In essence, the patent holder has obtained the patent through competition on the merits. In order to reward the patent holder for his innovation, he is sheltered from competition for 20 years.<sup>67</sup> The patent is granted to ensure that the innovator can recoup its investment by enabling it to reap monopoly profits for a limited period of time, thus fostering innovation and increasing dynamic efficiencies.<sup>68</sup> In return, the innovation goes into the public domain after patent expiry so that society can benefit from this innovation by copying it.<sup>69</sup> There is therefore an observable trade-off between rewarding the innovator and allowing society to benefit from this innovation.<sup>70</sup> However, just as in the market liberalisation scenario above, the patent holder is also likely to have gained additional advantages such as an established customer base, a possible advanced distribution network and network effects.

Drawing an analogy with the decision in *Post Denmark*, if it is accepted that a former conferred legal monopoly can have an impact on the special responsibility of the dominant undertaking to not impair undistorted competition after the expiry of such monopoly, special focus should therefore be placed on conduct that is based on the advantages that the dominant undertaking acquired because of the sheltered nature of a legal monopoly. Equally, focus should be afforded to the advantages that the dominant firm continues to receive beyond the expiry of the monopoly. In terms of early entry agreements, this would mean that the focus of antitrust scrutiny should concentrate on the brand company's conduct with regards to the exploitation of the generic first mover advantage post-patent expiry and the

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<sup>66</sup> Stanley M Besen and Raskind Leo J. 'An introduction to the law and economics of intellectual property' (1991) 5 *The Journal of Economic Perspectives* 3, 7.

<sup>67</sup> Bronwyn H Hall, 'Patents and patent policy' (2007) 23 *Oxford Review of Economic Policy*, 568, 568.

<sup>68</sup> *Ibid.* 568.

<sup>69</sup> *Ibid.* 571.

<sup>70</sup> Besen and Raskind Leo J. (n 66) 6.

control gained over the generic company prior to patent expiry, which are both aimed at increasing generic prices to the detriment of the consumer.

### 3.2. Exclusive sourcing obligations

The European Commission has defined exclusive purchasing obligations as those that require:

*‘a customer on a particular market to purchase exclusively or to a large extent only from the dominant undertaking. Certain other obligations, such as stocking requirements, which appear to fall short of requiring exclusive purchasing, may in practice lead to the same effect.’<sup>71</sup>*

According to the pharmaceutical sector inquiry, a number of generic companies that entered into an early entry agreement and agreed to an exclusive sourcing agreement were required to purchase from the brand company all the requirements that are necessary for the drug.<sup>72</sup> One of the main requirements in the production of a drug – and certainly the most important – is the active pharmaceutical ingredient (API).<sup>73</sup> The API is also a significant cost factor. In the case of generic oral solid drugs, for example, the cost of the API constitutes 40-50% of the production costs.<sup>74</sup>

The global API market is generally very competitive. A descriptive study in 2009 found that, internationally, 2,056 manufacturers operate 3,700 manufacturing sites.<sup>75</sup> Due to the large number of API manufacturers in existence, there has been

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<sup>71</sup> European Commission, *Guidance on the Commission's enforcement priorities in applying Article 82 of the EC Treaty to abusive exclusionary conduct by dominant undertakings* [2009] OJ C45/02 Recital 33.

<sup>72</sup> European Commission (n 9) para 826.

<sup>73</sup> Generally drugs are composed of two different components. The active pharmaceutical ingredient is the chemical substance that produces the desired effect on the body. The second component, called the excipient, is the substance of which the actual drug consists. This can be for example a liquid or a powder. See <[http://www.pharma-ingredients.com/active\\_pharmaceutical\\_ingredients/](http://www.pharma-ingredients.com/active_pharmaceutical_ingredients/)>.

<sup>74</sup> Janet Bumpas and Ekkehard Betsch, ‘Exploratory Study on Active Pharmaceutical Ingredient Manufacturing for Essential Medicines, HNP Discussion Paper’ <<http://siteresources.worldbank.org/HEALTHNUTRITIONANDPOPULATION/Resources/281627-1095698140167/APIExploratoryStudy.pdf>> 10.

<sup>75</sup> *Ibid.* 11.

a widespread trend towards firms specialising in the production of a specific type or range of APIs. Companies often choose to focus on manufacturing for certain therapeutic areas, producing more complex APIs, or producing large amounts of API for generic purposes.<sup>76</sup> In fact, every API is manufactured by a number of different companies,<sup>77</sup> including larger generic companies that have their own API production facilities.<sup>78</sup> Following a recent survey conducted by the World Health Organization, the price differentials between the different manufacturers of the same API were found to be very significant. In some cases, the price difference between the cheapest manufacturer and the most expensive was up to 700%.<sup>79</sup> It should be mentioned that the most extreme example concerns HIV drugs, which is likely to be a special case. Therefore, while these price differentials might not be representative of the entire API market, they definitely shed some light on the potential savings that generic pharmaceutical companies can realise by choosing the right API manufacturer.

The exclusive sourcing obligation of the generic early entrant could therefore lead to the foreclosure of the API market. Post-patent expiry, competing API manufacturers can produce the API upstream but are prevented from supplying it to the early entered generic company, due to the exclusive sourcing obligation, imposed on the early generic entrant by the brand company.

This does not necessarily lead to a complete foreclosure of the market for this specific API as other generic companies are likely to enter the market subsequently and these new entrants will also require the relevant API for the drug production. But one should bear in mind that the market share of subsequent generic entrants is significantly smaller compared to the first generic entrant.<sup>80</sup> This

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<sup>76</sup> Ibid. 12.

<sup>77</sup> See <[www.api-data.com](http://www.api-data.com)> This database offers the possibility to search for the available manufacturers of a large number of APIs. A random search has shown that up to 20 different companies manufacture the same API.

<sup>78</sup> i.e. Teva Pharmaceutical Industries Ltd A.P.I. Division; Lupin Ltd; CIPLA Ltd; Mylan Laboratories Ltd; Dr Reddys Laboratories Ltd.

<sup>79</sup> WHO, *'Sources, quality and prices of active pharmaceutical ingredients of antiretroviral drugs: Results of a 2012 WHO survey'* (World Health Organization, Geneva, 2012) 10.

<sup>80</sup> It has been shown that the first generic entrant has a significant first-mover advantage over subsequent entrants. The first generic entrant has a stable increase in market share in the first 4 years after entry of an average 34 per cent, whereas the second entrant only has a 10 per cent



is likely to have an impact on subsequent generic entrants' demand for API. API manufacturers might therefore find it difficult to realise economies of scale, which is an important factor in the high-volume, low-margin business of API production.<sup>81</sup> It may only be viable for the competing API manufacturers to enter the market after the exclusive sourcing obligation is terminated or a critical mass of subsequent generic companies have entered downstream, so that economies of scale can be realised. In return, this might have an impact on the early generic entrant's production costs, as it is not able to source the cheapest API available which indirectly affects the price customers have to pay. The early generic entrant is unlikely to oppose this obligation as it is part of the commercial consideration between the brand company and the early generic entrant. However, the obligation is likely to have a negative effect on the generic price and, in turn, on consumer welfare.

Despite not being obliged to use the same API manufacturer as the early generic entrant, the subsequent generic entrants may not initially have any other choice. This causes subsequent generic prices to become higher than in a competitive environment, which is detrimental to consumer welfare.

So the question that needs to be posed is whether the exclusive sourcing obligation imposed by the brand company on the early generic entrant constitutes an infringement of Art. 102 TFEU. The remainder of this section discusses this question and separately considers the situation prior to patent expiry and post-patent expiry.

### **3.2.1. The situation prior to patent expiry**

Early entry agreements are generally stipulated whilst the relevant brand drug is still under patent protection. This being the case, the generic company's obligations under the early entry agreement, such as the exclusive sourcing of the API, could be permissible as such conduct could be regarded the mere exercise of the rights

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increase in market share in the same period. Aidan Hollis, 'The importance of being first: evidence from Canadian generic pharmaceuticals' (2002) 11 *Health Economics* 723, 729.

<sup>81</sup> Bumpas and Betsch (n 74) 10.

conferred by patent policy. Generally speaking, a patent entitles its holder to exclude others from using that property right.<sup>82</sup> The ECJ has repeatedly found with regard to the abuse of a dominant position that the exercise of an intellectual property right cannot in itself constitute an abuse.<sup>83</sup> Yet the Court has also clarified that conduct that is based on the exercise of an intellectual property right is not excluded from antitrust scrutiny and, thus, cannot be used as sole justification for otherwise anticompetitive types of conduct.<sup>84</sup> To establish whether a certain type of conduct should be subject to an Art. 102 TFEU review or rather permissible due to the exclusionary nature of the intellectual property right, it has to be determined whether the conduct at issue is within the scope of the patent. The core rights that are within the scope of the patent are sometimes referred to as the ‘essential functions’.<sup>85</sup>

As long as the conduct stays within this scope, it should be regarded as procompetitive and should therefore be permitted.<sup>86</sup> This kind of exploitation of an exclusive right is viewed as competition on the merits as it fosters dynamic competition and the development of new products.<sup>87</sup>

The conduct can exceed the scope of the exclusive right in different ways. For example, the conduct can go beyond what is necessary to exercise the exclusive right if the dominant undertaking uses the market power it has gained in one market – due to the exclusive right – to leverage market power in an adjacent market that is not covered by the exclusionary power of the same exclusive right. This exceeds the breadth of the exclusive right and, in other words, the conduct attempts to exert an exclusionary effect on subject matter is not covered by the exclusive right. However, the scope of the exclusive right also has a temporal

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<sup>82</sup> Robert O'Donoghue and A. J Padilla, *The law and economics of Article 82 EC* (Hart, Oxford, 2006) 415.

<sup>83</sup> Cases C-241-1/91 P, *RTE & ITP v. Commission* [1995] ECR I-743 para. 49.

<sup>84</sup> *Ibid.* para. 48.

<sup>85</sup> O'Donoghue and Padilla (n 82) 436; “[A]ccording to the case-law of the Court of Justice and [General Court] [...] [t]he crucial point is whether the conduct goes beyond what is necessary to fulfil the essential function of the exclusive right as permitted in Community Law.” *DSD* (Case COMP D3/34493) Commission Decision 2001/463/EC [2001] OJ 2001 L166/1 para. 144.

<sup>86</sup> O'Donoghue and Padilla (n 82) 436.

<sup>87</sup> Steven D Anderman, ‘The IP and Competition Interface: New Developments’ in Steven D Anderman and Ariel Ezrachi (eds), *Intellectual property and competition law: New frontiers* (Oxford University Press, Oxford, 2011) 18.

element. For example a patent is granted for a period of 20 years. If the conduct exceeds the period of protection which is granted to the dominant undertaking, one can also argue that the conduct goes beyond the scope of the exclusive right and should be put under the scrutiny of Art. 102 TFEU.

So it has to be determined whether the exclusive sourcing obligation in the early entry agreement between the brand company and the generic company is within the scope of the patent on which the early entry agreement is based. The exclusive sourcing obligation at issue concerns the supply of all necessary requirements of the API needed for the production of the generic version of the drug. Given that the API is the core ingredient of the drug and the innovative compound that has the actual therapeutic effect on the body, it is generally covered by the brand company within the basic patent. Typically, the brand company either produces the API itself or provides an API manufacturer with the licence to produce the API for the brand company. It is within the scope of the basic patent and thus accepted by competition law that the brand company prevents other API manufacturers from 'copying' its API.<sup>88</sup> So if the brand company can legally hinder other companies from producing the API in the first place during patent protection, the outcome should be the same for exclusive sourcing obligations for the generic company, forcing it to purchase all necessary API from the brand company. The outcome is the same – the generic company purchases its requirements of API from the only API manufacturer.

### **3.2.2. The situation post-patent expiry**

This stance towards exclusive sourcing obligations changes once the patent on which the early entry agreement is based expires. At this point in time, other API manufacturers can produce the API in question upstream and could compete for the generic company's demand downstream. Such competition would only be fruitful if the generic company were freely able to choose the API supplier.

In a number of cases, the early entering generic company is bound by the exclusive sourcing obligation beyond the expiration of the patent. Exclusive

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<sup>88</sup> Ibid.

sourcing obligations are stipulated for an average period of 3.7 years.<sup>89</sup> However, in the majority of cases, the contracting parties tend to enter into early entry agreements within 12 months prior to patent expiry,<sup>90</sup> thus exceeding the patent life by, on average, at least two years. From the moment the patent expires, exclusive sourcing obligations should be put under antitrust scrutiny and it needs to be established whether such obligations are likely to foreclose the relevant market. The remainder of this section therefore sets out the European Commission's approach to exclusive sourcing obligations outlined in its Guidance on its enforcement priorities on the application of Art 102 TFEU to abusive exclusionary conduct,<sup>91</sup> as well as the EU courts' position towards these obligations based on their case law.

According to its Guidance, the European Commission focuses on cases in which the exclusive sourcing obligations have the *effect* of preventing the entry or the expansion of competitors – in this case, competing API manufacturers.<sup>92</sup> This foreclosing effect is established by determining whether competitive pressure could have been exerted by competitors in the absence of the exclusive dealing obligation. It is not necessary that potential competitors are able to compete for the entire demand of the customers.<sup>93</sup> It might be the case that the dominant undertaking is an unavoidable trading partner and that its brand is a 'must stock item', either because it is preferred by many final consumers or because the capacity constraints on the other suppliers are such that a part of demand can only be provided by the dominant supplier.<sup>94</sup> An important factor for the establishment of the foreclosing effect is the duration of the exclusive dealing obligation. The longer the duration, the more likely the foreclosure.<sup>95</sup> Such a foreclosure must ultimately have the capability of causing consumer harm in order to be anticompetitive. This consumer

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<sup>89</sup> European Commission (n 9) para. 844.

<sup>90</sup> Ibid. Figure 126.

<sup>91</sup> European Commission (n 71).

<sup>92</sup> Ibid. Recital 34.

<sup>93</sup> Ibid. Recital 36.

<sup>94</sup> Ibid. Recital 36 citing Case T-65/98 *Van den Bergh Foods Ltd v Commission* [2003] ECR II-4653.

<sup>95</sup> European Commission (n 71) Recital 36.

harm needs to be independently verified,<sup>96</sup> but there is no need to prove actual harm, as the law is meant to prevent harm before it is done.<sup>97</sup> This last statement seems to contradict the European Commission's proclamation of pursuing a more effects-based approach. It is not possible, or at least unnecessary, to show actual anticompetitive effects if it is sufficient to prove that a certain type of conduct has the mere capability of leading to consumer harm. Although the European Commission has been criticised for not applying a pure effects-based analysis in its Guidance,<sup>98</sup> this discrepancy can be explained by the limitation posed by the relevant case law. The European Commission may wish to focus on economic effects and proof of likely consumer harm but the case law simply does not allow much room for such analysis.<sup>99</sup>

Exclusive purchasing agreements were initially regarded by the ECJ as per se illegal in *Hoffmann-La Roche v Commission*. The Court expressly stated that:

*“an undertaking which is in a dominant position on a market and ties purchasers — even if it does so at their request — by an obligation or promise on their part to obtain all or most of their requirements exclusively from the said undertaking abuses its dominant position within the meaning of Article [102 TFEU], whether the obligation in question is stipulated without further qualification or whether it is undertaken in consideration of the grant of a rebate.”*<sup>100</sup>

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<sup>96</sup> O'Donoghue and Padilla (n 82) 361.

<sup>97</sup> Anderman (n 87) 20.

<sup>98</sup> Marsden argues that the European Commission stride towards a more-effects based approach is hampered by two fundamental assumption which have not been adequately addressed by the European Commission in its Guidance: (1) The assumption that dominance inevitably harms the competitive structure of the market. The guidance fails to offer an analysis of the question whether dominance actually leads to less competitive constraint by rivals. (2) The assumption that foreclosure is anticompetitive itself without the necessity to prove that consumer harm is likely. Philip Marsden, 'Some outstanding issues from the European Commission's Guidance on Article 102: Not-so-faint echoes of Ordoliberalism' in Federico Etro and Ioannis Kokkoris (eds), *Competition law and the enforcement of article 102* (Oxford University Press, Oxford, 2010) 55, 56.

<sup>99</sup> Ibid. 54. This statement should not suggest that EU jurisprudence creates precedent. It rather expresses the view that the EU Courts are reluctant fully endorse the European Commission's efforts to follow a more effects-based approach.

<sup>100</sup> *Hoffmann-La Roche* (n 58) 89.

Whereas the Court referred in vague terms to “all or most of their requirements” with regards to the finding of an exclusive purchasing agreement that infringes Art. 102 TFEU, this requirement was subsequently clarified. Under the Vertical Block Exemption Regulation, a non-compete obligation<sup>101</sup> is defined as an obligation that requires the buyer to purchase at least 80 per cent of its requirements from one source.<sup>102</sup>

What is also important to note from the abovementioned quote in *Hoffmann-La Roche* is the fact that it does not matter whether the exclusive purchasing obligation was imposed on the buyer. Even if the buyer requests such an obligation to be part of the agreement, it can potentially constitute an infringement of Art. 102 TFEU.<sup>103</sup>

In *Van den Bergh Foods*, the General Court seemed to move away from the formalistic approach holding that the exclusive dealing arrangement at issue was not abusive per se, but amounted to being abusive due to the fact that it had “*the effect [...] of preventing competing manufacturers from gaining access to the relevant market*”.<sup>104</sup> This can be seen as support of the European Commission’s finding in the same case, where it was decided that:

*“for the purpose of applying Article [102 TFEU], the circumstance surrounding the [exclusive dealing] agreements and particularly their effect on the structure of competition in the relevant market must be taken into account in establishing the existence of an abuse.”*<sup>105</sup>

However, the General Court again relied in subsequent cases on the ECJ’s judgment in *Hoffmann-La Roche* and reverted to the more formalistic view of exclusive

<sup>101</sup> Non-compete obligations can be used interchangeably with exclusive purchasing obligations in this context, as the intended outcome of both obligations is the same – requiring the buyer to obtain at least 80 of its requirements from one source.

<sup>102</sup> *Commission Regulation (EC) No 2790/1999 on the application of Article 81(3) of the Treaty to categories of vertical agreements and concerted practices* (1999) OJ L 336. Art. 1(b) replaced by *Commission Regulation (EU) No 330/2010* (n 4). Art.1 (d).

<sup>103</sup> Richard Whish, *Competition law* (7<sup>th</sup> edn Oxford University Press, Oxford, 2012) 684.

<sup>104</sup> *Van den Bergh Foods Ltd v Commission* (n 94) para. 160.

<sup>105</sup> *Van den Bergh Foods Ltd* (Case Nos IV/34.073, IV/34.395 and IV/35.436) Commission Decision 98/531/EC [1998] OJ L246/1 para. 268.

purchasing agreements or on fidelity rebates that indirectly amount to exclusive purchasing agreements in *Solvay SA v Commission*,<sup>106</sup> and *Imperial Chemical Industries Ltd v Commission*.<sup>107</sup>

It is argued that this divergent and more effects-based approach in *Van den Bergh Foods* is owed to the fact that the Commission had brought the proceedings under both Art. 101 TFEU and Art. 102 TFEU.<sup>108</sup> If proceedings are brought under both articles the same approach should be taken, which arguably led to consideration of the more economic approach of Art. 101 TFEU in Art. 102 TFEU.<sup>109</sup> This line of argument would explain the General Court's different approach to a seemingly similar abuse. Fundamentally, this would mean that the Court has not reverted to more a formalistic approach after *Van den Bergh Foods* but, rather, saw the necessity for a different approach if the European Commission takes a "dual approach" in its investigation.

The following considers whether the EU courts' approach has changed as a reaction to the European Commission's Guidance in 2009. As will be shown, this is unfortunately not the case. During the modernisation process of the European Commission's approach to Art. 102 TFEU, the ECJ had the chance to move to a more effects-based approach in relation to fidelity rebates in *British Airways v Commission*.<sup>110</sup> However, the Court rejected British Airways' plea that the General Court had made an error of law inasmuch as it did not examine direct consumer harm, by reiterating that it is sufficient to show that the conduct in question had a negative effect on the competitive structure and therefore led to a distortion of competition.<sup>111</sup> In its recent judgment in *Tomra Systems v Commission*, the ECJ reaffirmed this position by stating that it is:

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<sup>106</sup> Case T-57/01 *Solvay SA v. Commission* [2009] ECR II-4621. para. 365 overruled only on procedural appeal on right to the access of files by Case C-109/10P, *Solvay SA v. European Commission* [2011] ECR I-10329 para. 51-73.

<sup>107</sup> Case T-66/01 *Imperial Chemical Industries Ltd v. Commission* [2009] ECR II-2631. para. 315.

<sup>108</sup> Jones and Sufrin (n 61) 452.

<sup>109</sup> *Ibid.* citing Ekaterina Rousseva, *Rethinking exclusionary abuses in EU competition law* (Hart, Oxford and Portland 2010) 431-453.

<sup>110</sup> Case C-95/04 P *British Airways plc v EC Commission* [2007] ECR I-2331.

<sup>111</sup> *Ibid.* para. 106, 107.

*‘unnecessary to undertake an analysis of the actual effects of the rebates on competition given that, for the purposes of establishing an infringement of Article 102 TFEU, it is sufficient to demonstrate that the conduct at issue is capable of having an effect on competition.’<sup>112</sup>*

It follows from this judgment that a decision by the European Commission in relation to a fidelity rebate scheme will not be overruled by the EU courts, even if the European Commission investigates the actual effects of a rebate scheme and commits an error in its assessment.<sup>113</sup> Such an analysis would merely be complementary, as the European Commission does not have to show actual effects that prevent an ‘as efficient’ competitor from competing on the relevant market.<sup>114</sup>

The fact that most of the discussed recent case law relates to fidelity rebates and not to direct exclusive purchasing obligations should not compromise the applicability of the case law to the latter. Fidelity rebates are regarded in the European context as instruments that induce customers not to purchase a certain product from competitors of the dominant undertaking in an attempt to drive these competitors out of the market. In contrast, exclusive purchasing obligations do not have to induce customers in the same way, as the obligation stipulates that the customer has to buy all or most of his requirements of a certain product from the dominant undertaking. An exclusive purchasing obligation does not even give the customer the theoretical choice not to purchase all requirements and to waive the potential rebate. It would therefore be logical if the EU courts were to take a similarly formalistic approach to exclusive purchasing obligations, as they are even more likely to be capable of distorting competition.

### **3.2.3. Conclusion**

It can therefore be concluded that the exclusive sourcing obligation as part of the early entry agreement stipulated between the brand company and the generic

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<sup>112</sup> Case C-549/10P *Tomra Systems and Others v Commission* (ECJ, 19 April 2012) para.79.

<sup>113</sup> Ariel Ezrachi, *EU competition law: An analytical guide to the leading cases* (3<sup>rd</sup> edn Hart, Oxford, 2012) 213.

<sup>114</sup> *Ibid.*



company is only partially within the scope of the underlying patent. As long as the patent is valid and has not expired, an exclusive sourcing obligation constitutes an exercise of the exclusive right which prevents the copying of the patent protected innovation. At the point of patent expiry, the exclusive sourcing obligation should be put under antitrust scrutiny. Following the discussion of the relevant case law, it is clear that such an obligation is likely to infringe Art. 102 TFEU if the generic company is obliged to purchase more than 80 per cent of API from one source. Proving actual anticompetitive effects is, for now, only likely to be necessary if the European Commission has brought proceedings against the brand company in relation to Art. 101 TFEU and Art. 102 TFEU, as this might at least sway the General Court to consider a more effects-based analysis following its judgment in *Van den Bergh Foods*.

Despite the criticism of the EU court's formalistic approach to exclusive purchasing agreements, the distinction between exclusive agreements prior to patent expiry and post-patent expiry makes sense from a policy perspective. The central argument for granting a patent is to incentivise companies to invest in innovation and to spur dynamic competition. The bounty for such investment is the prospect of large future profits and the possibility of avoiding competition from rival firms.<sup>115</sup> The reliance on these prospects, which might lead some firms to take risky decisions regarding expensive innovations *ex ante*, should not be unsettled *ex post*, as this may have a stifling effect on future dynamic competition.<sup>116</sup> However, the pre/post-patent distinction does not interfere with or diminish the prospects of innovating companies. *Ex post*, the companies rely on the fact that the patent is granted for a period of 20 years in which they can recoup their investments and reap profits. After these 20 years have passed, the companies undoubtedly still make profits but they cannot expect them to be unchallenged, as they are no longer part of the deal with society. Thus it is acceptable to treat the same kind of agreement differently post-patent expiry as opposed to prior to patent expiry.

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<sup>115</sup> O'Donoghue and Padilla (n 82) 453.

<sup>116</sup> It is this difficult balance between short-term static efficiencies and long-term dynamic efficiencies that makes it problematic to impose a duty to deal on innovating companies.

### 3.3. Single branding agreements

Having analysed the potential foreclosure of the upstream market for API production post-patent expiry and its potential consequence of creating higher generic drug prices, this section now turns to an investigation on the impact of single branding agreements on the downstream market. This examination largely concerns conduct post-patent expiry. In one instance, potential anticompetitive foreclosure prior to patent expiry is discussed – namely the hampered access to the market for subsequent generic entrants that are not willing to enter “at their own risk” prior to patent expiry.

The term ‘single branding agreements’ itself is not used by the European Commission in its pharmaceutical sector inquiry. It rather describes supply and distribution agreements between the brand company and the early generic entrant that includes exclusivity clauses and non-compete obligations in terms of territorial restrictions as well as non-territorial restrictions. Yet, taking all of these clauses together, their effect amounts to a single branding agreement. Generalising these clauses in this way is beneficial to the legal analysis itself, as the case law of the EU courts as well as the decision practice of the European Commission offer a number of decisions and judgments that can be used as guidance for the application of Art. 102 TFEU to early entry agreements.<sup>117</sup>

According to the pharmaceutical sector inquiry, 29 out of the 87 identified early entry agreements contained non-compete clauses.<sup>118</sup> 25 of these agreements also restricted the generic company’s active sales outside the territory that was covered by the agreements, therefore preventing the company from advertising and actively searching for customers outside the territory.<sup>119</sup> What is more common in these agreements is the fact that the brand company provides the generic company with a copy of its own market authorisation or with the underlying

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<sup>117</sup> In contrast, an investigation of the specific non-compete obligation could not be supported by the same amount of case-law. Non-compete clauses have only been rarely addressed by the Courts and if so exclusively under Art. 101 or within merger investigations. Thus it might have been necessary to develop novel theory of harm. This would have been within the scope of Art. 102 TFEU, as the list of types of abuse is non-exhaustive, but would not have contributed to the legal certainty of the application of Art. 102 TFEU. Such a step should only be taken if absolutely necessary.

<sup>118</sup> European Commission (n 9) para. 827.

<sup>119</sup> *Ibid.* para. 848.

documentation that enables the generic company to apply for its own market authorisation. However, the copy of the market authorisation or the underlying documentation is contractually restricted to a certain territory.<sup>120</sup> In doing so, the brand company has not actually stipulated an exclusive agreement that is restricted to a certain territory, but these agreements have a similar effect. The generic company would technically be able to apply for its own marketing authorisation for other territories, but such behaviour would incur significant time and cost. To be able to apply for a marketing authorisation, the generic company would have to prove that its generic drug is bioequivalent to the brand drug, which is done by means of human clinical trials. Aside from the length of these trials, they also constitute the lion's share of the cost for generic entry.<sup>121</sup> So despite the possibility existing in principle, such an extension of the territorial coverage is unlikely to be profitable and thus not probable. Additionally, 29 agreements contained a non-compete clause with respect to competing products. The generic company is not only prevented from marketing alternative products containing the same API or any of its salts,<sup>122</sup> but it is also barred from marketing alternative competing products from a different source in the territory concerned and within the time frame of the agreement.<sup>123</sup> So potentially the generic company not only has to refrain from sourcing all required ingredients for the product from anyone other than the brand company, it is also explicitly or effectively hindered from actively selling the generic drug outside the agreed territory and cannot market competing products during the duration of the agreement.

Just as in the case of exclusive sourcing obligations, it has to be kept in mind that a single branding obligation as part of the early entry agreement is to be regarded as a legitimate exercise of the underlying patent right. The possibility of commercialisation is at the core of every patent and should not be interfered with by antitrust rules. However, just as with regard to the exclusive sourcing obligation discussed above, this situation changes at the time of patent expiry. Upon the

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<sup>120</sup> Ibid. para. 849.

<sup>121</sup> See chapter III sec. 3.1.

<sup>122</sup> A salt is a part of the patented molecule and thus also covered by the patent.

<sup>123</sup> European Commission (n 9) para. 848.

expiration of the patent term, the patented information is in the public domain and can no longer be enforced by the patent holder who, in turn, can no longer exclusively commercialise the invention. It is therefore only consequential that a single branding obligation that is based on the exclusionary power of a patent loses its legal basis with its expiry. This is also acceptable from a policy perspective. The patent owner is allowed to exploit his patented invention for the granted period of time. Any exclusive agreements that were originally based on the exclusionary power of a patent, but that last longer than the patent life, should be regarded as commercial considerations that should be subject to antitrust scrutiny.

The fact that generic companies seem to accept single branding obligations that go beyond the period of patent protection might be explained by the fact that, in some cases, the generic companies are provided with a copy of the marketing authorisation of the brand company. Initially, obtaining a copy of such an authorisation might be desirable, as it is cost-reducing and time-saving, but it also provides the brand company with significant leverage against the generic company. With the withdrawal of the authorisation by the brand company, the generic company would have to cease marketing the drug until it has acquired its own marketing authorisation, a process that is very time-consuming and costly. In essence, this would effectively lead to the exit of the generic company from the market. These circumstances are likely to lead to the generic company's acceptance of less profitable contract terms post-patent expiry. The key question, however, is not whether the early generic entrant is harmed but rather whether the market is foreclosed for subsequent entry which could lead to higher prices due to reduced competitive pressure.

Single branding agreements post-patent expiry could therefore be scrutinised on the basis of their potential for: (a) the anticompetitive foreclosure of subsequent generic entrants and competing brand companies, and (b) the restriction of choice for the early generic entrant which, indirectly, also has an impact on competing brand companies that want to cooperate with the same generic company. These two scenarios will be discussed in turn. Again, one noted exception to this general distinction between conduct prior and post-patent expiry

is the impeded access of subsequent generic entrants that are willing to enter “at their own risk” prior to patent expiry in order to challenge the relevant patent or because they believe that their generic drug is not infringing the relevant brand patent. The discussion below shows that such an examination is not at odds with the general policy consideration that allows the brand company to exploit its intellectual property right during the protection period.

### 3.3.1. Anticompetitive foreclosure

Anticompetitive foreclosure is defined by the European Commission in its Guidance as:

*‘a situation where effective access of actual or potential competitors to supplies or markets is hampered or eliminated as a result of the conduct of the dominant undertaking whereby the dominant undertaking is likely to be in a position to profitably increase prices to the detriment of consumers.’<sup>124</sup>*

Prior to patent expiry, a single branding agreement between the brand company and the early generic entrant could hamper the market access of subsequent generic entrants that want to enter the market “at their own risk” prior to patent expiry.<sup>125</sup> A generic company’s risk is the likelihood of being sued for patent infringement by the brand company. This likelihood is determined by the strength of the patents that would be infringed by the entering generic company and the brand company’s willingness to enforce its patents. If the generic company believes that it does not infringe the brand company’s patents or that these patents are invalid, it might take the risk of entering prior to patent expiry. The incentive for taking this risk is the prospective increase in generic profit that is gained from entering as early as possible. However, this incentive could be significantly reduced by an early entry agreement, especially if the agreement is concluded with a

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<sup>124</sup> European Commission (n 71) Recital 19.

<sup>125</sup> See chapter III sec. 2.3.2 Following the European regulatory regime, generic companies can obtain marketing authorisation prior to patent expiry regardless of existing patents of the brand company.

generic company that has a large distribution network.<sup>126</sup> Pharmacies that are part of the distribution network of a large generic company with a diverse product portfolio are likely to purchase most of their necessary supply of generic drugs from this generic company. Not only is it likely to be more cost efficient to purchase most of the supplies from a single source, but the generic company might also incentivise the pharmacies to do so by offering a rebate scheme.<sup>127</sup> Furthermore, it should be noted that pharmacies generally tend to stock only one generic product.<sup>128</sup> With such an early generic entrant already present on the market that provides a large number of pharmacies with the generic drug, the demand for a second generic drug is already significantly reduced. A subsequent generic company might therefore be unwilling to take the risk of entering prior to patent expiry and will instead wait for the relevant patent to expire. The reduced demand is still the same after patent expiry, but the subsequent generic company no longer runs the risk of incurring legal costs following a patent infringement lawsuit.

Apart from the fact that this outcome contradicts general patent policy,<sup>129</sup> the brand company could thereby distort the competitive process on the market for generic drugs post-patent expiry. If the brand company would not have entered into such an agreement, it is likely that the simultaneous entry of several generic companies would have occurred at the time of patent expiry. By concluding an early

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<sup>126</sup> The generic company's distribution network is an important factor that is considered by the brand company in its decision of the appropriate generic partner. European Commission (n 9) para. 729. Additionally it has been stated in a brand company's strategy document that the '*Launch [of a generic drug] via an early entry agreement with main players in the distribution channel [prevents] disproportionate discounting of [other generic drugs]*' by means of controlling the sales for a large part of the market beyond loss of exclusivity. European Commission (n 9) para 825.

<sup>127</sup> i.e. TEVA's rebate scheme offers pharmacies the nett-price for all its products that are included in the scheme, if the pharmacy spends at least £2500 per months. Teva also offers additional discounts of 3% and 5% once the pharmacy reaches certain expenditure thresholds (£4500+ and £6000+ respectively). TEVA UK Limited, *TevaTwo*, <<http://tevascheme.tevauk.com/pharmacy/tevatwo>>.

<sup>128</sup> Information obtained through discussions with a Professor in the School of Pharmacy at the University of East Anglia.

<sup>129</sup> A patent gives its owner not the "right to exclude" but rather the "right to try to exclude". Carl Shapiro, 'Antitrust limits and patent settlements' (2003) 34 *Rand Journal of Economics* 391, 395; every patent should be challengeable. Although it is true that an early entry agreement does not actually foreclose the possibility to patent challenge, it is nonetheless likely to have that effect. A generic company will not enter at risk without gaining an incentive that outweighs the increased costs of patent litigation. Thus the patent owner enjoys the full period of patent protection regardless of the merit of the patents, by minimising the incentives for a generic company's patent challenge.

entry agreement, the brand company has changed the simultaneous entry game into a sequential entry game. Even if several generic companies enter the market simultaneously at the time of patent expiry, the early generic entrant is in an advantageous position by virtue of already being present in the market. Indeed, it has already been shown as part of the discussion of market definition<sup>130</sup> and the theory of harm<sup>131</sup> that the generic first-mover advantage can potentially have a significant impact on the market structure itself. Empirical evidence has shown that the longer a generic drug is prescribed by doctors, the less likely it is that these doctors will switch to a new generic drug.<sup>132</sup> Using the example of antiepileptic drugs, it has been shown that prescribing doctors might only switch their patients to a generic drug on one occasion, because of the fear of significant adverse side-effects.<sup>133</sup> This first-mover advantage of the early generic entrant can translate into a long-lasting effect on the market share of the generic companies on the market. Empirical evidence has shown that the early generic entrant has a market share of about 30 per cent over several years, as opposed to a market share of about 10 per cent for the subsequent generic entrant which declines over time.<sup>134</sup> Depending on the market size and the relevant minimum efficient scale, there may be the potential for the brand company to foreclose the market.

In addition, a single branding agreement that continues to operate beyond the life of the patent could also hamper the market access of competing brand companies by blocking the early generic entrant from producing and distributing the generic drugs of competing brand drugs. This would force the competing brand company to “use” another generic company with a potentially smaller distribution network. Having to use a potentially less efficient generic company as an early generic entrant in order to distribute the generic version not only leads to a likely increase

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<sup>130</sup> See chapter I section 4.1.1.1.

<sup>131</sup> See chapter II section 2.1.1.2.

<sup>132</sup> See chapter II section 2.1.1.2. (i).

<sup>133</sup> See Chapter I p.20, 21 and section 4.1.1.2.

<sup>134</sup> Hollis (n 80) 729.

in cost – in accordance with the theory of raising rivals’ costs<sup>135</sup> – but may also result in the potential foreclosure of a significant part of the market; assuming that pharmacies only stock one generic version and are incentivised to purchase the majority of its supply from one generic company.<sup>136</sup>

The question is how this potential anticompetitive foreclosure would be addressed by the European Commission and the EU courts. According to the European Commission’s Guidance,<sup>137</sup> its assessment of anticompetitive foreclosure relies on factors such as: the position of the dominant undertaking; the condition of the relevant market including the existence of economies of scale; the position of competitors; the position of consumers and input suppliers; the extent of the alleged abusive conduct; and possible evidence of actual foreclosure including direct evidence of any exclusionary strategy.<sup>138</sup> In relation to retroactive loyalty-inducing rebates, the European Commission further states that:

*‘as with exclusive purchasing obligations, the likelihood of anti-competitive foreclosure is higher where competitors are not able to compete on equal terms for the entire demand of each individual customer.’<sup>139</sup>*

It is therefore necessary to assess the ‘contestable share’ of the market in order to determine how much of the customer’s purchase requirements can be switched to the competitor.<sup>140</sup> One could therefore assume that the European Commission determines the contestable portion of the market in terms of minimum efficient scale. This would be a sensible approach as it would consider a market to be foreclosed if the contestable part of the market was not large enough for an as efficient competitor to viably enter.

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<sup>135</sup> See generally Salop and Scheffman (n 23); Krattenmaker and Salop (n 23); Salop and Scheffman (n 23).

<sup>136</sup> Information obtained through discussions with a Professor in the School of Pharmacy at the University of East Anglia.

<sup>137</sup> European Commission (n 71).

<sup>138</sup> Ibid. Recital 20.

<sup>139</sup> Ibid. Recital 39.

<sup>140</sup> Ibid. Recital 42.



The EU courts, however, seem to have once again opted for a more formalistic approach to the question of what determines a contestable market with regard to anticompetitive foreclosure. In the case of *Tomra Systems v Commission*,<sup>141</sup> which was recently upheld by the ECJ,<sup>142</sup> it was found that:

*‘the customers on the foreclosed part of the market should have the opportunity to benefit from whatever degree of competition is possible on the market and competitors should be able to compete on the merits for the entire market and not just for a part of it [and that] it is not the role of the dominant undertaking to dictate how many viable competitors will be allowed to compete for the remaining contestable portion of demand.’<sup>143</sup>*

The General Court had already stated in its judgment that the fact that a limited number of competitors can still enter the market competing for the “non-foreclosed” contestable part of the market is not contrary to the finding of an abuse of Art. 102 TFEU. Competitors should be able to compete on the merits for the entire market and not just for the contestable part of it.<sup>144</sup> In addition, the General Court has found that the foreclosure of 40 per cent of the total demand is regarded as a restriction of competition on the relevant market.<sup>145</sup>

These findings have been subject to heavy criticism. In particular, the statement concerning the entirety of the market has been described as *‘one of the most extraordinary statements ever made in a competition law judgment’<sup>146</sup>* as, if

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<sup>141</sup> The fact that the exclusivity agreement in Tomra was achieved by means of retroactive rebates granted to the downstream firms does not impact the applicability of the judgment to the case of early entry agreements. It has already been held in *Hoffmann-La Roche* that the exclusive dealing agreement can either be reached by contractual stipulation or by means of offering rebates. This is only logical as a contractual agreement legally binds the contracting party, whereas a rebates merely induces an incentive for the party to buy exclusively from the supplier. It could theoretically choose to buy from a different supplier nonetheless. This possibility is not given in the case of stipulated exclusivity.

<sup>142</sup> *Tomra Systems and Others v Commission* (n 112).

<sup>143</sup> *Ibid.* 42

<sup>144</sup> Case T-155/06 *Tomra Systems ASA and Others v European Commission* [2010] ECR 00 para 241.

<sup>145</sup> *Ibid.* para. 243 also upheld by the ECJ *Tomra Systems and Others v Commission* (n 112) 44.

<sup>146</sup> Damien Geradin, Anne Layne-Farrar and Nicolas Petit, *EU competition law and economics* (1<sup>st</sup> edn, Oxford University Press, Oxford, 2012) 4.217.

read literally, it implies that the foreclosure of 10 per cent of the relevant market could be regarded as an abuse despite 90 per cent still being left contestable.<sup>147</sup>

Furthermore, the General Court's finding that the foreclosure of 40 per cent of the demand should be regarded as restriction of competition is heavily criticised, as the mere existence of a certain share of foreclosed demand does not necessarily indicate that other competitors are foreclosed from the market as a whole.<sup>148</sup> Again, this statement does not account for the potential competitive pressure that entrants might exert even though they might not be able to compete for the entire market. Interestingly, it has been suggested by one commentator in the United States that:

*'the introduction of important safe harbours for promotional contracts foreclosing less than 40% of distribution and for those shorter than one year in duration would significantly reduce false positives, providing certainty without significant offsetting risks of competitive harm.'*<sup>149</sup>

Based on these considerations, it would be more appropriate to determine whether the foreclosure of a relevant market is substantial by considering the market's minimum efficient scale. This means it would be necessary to consider the context of a relevant case before determining, on a case-by-case basis, whether the foreclosure would result in anticompetitive behaviour.<sup>150</sup>

In the case of *Intel*, the European Commission has indeed followed an effects-based approach using the 'as efficient competitor' analysis in order to show that the fidelity rebates in question were capable of causing or likely to cause anticompetitive foreclosure.<sup>151</sup> Despite devoting a substantial part of the decision to this analysis, the European Commission also added a formalistic reasoning to its

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<sup>147</sup> Ibid. 4.218; also Nicolas Petit, *The Future of the Court of Justice in EU Competition Law - New Role and Responsibilities* (2012) <<http://dx.doi.org/10.2139/ssrn.2060831>>, 11.

<sup>148</sup> Graciella Mieralles, 'Tomra: Exclusive Dealing and Rebates in the Light (and Shadows) of Dominance' (2011) 1 *European Journal of Risk Regulation* 129, 132.

<sup>149</sup> Joshua D Wright, 'Antitrust Law and Competition for Distribution' (2006) 23 *Yale Journal on Regulation* 169, 208.

<sup>150</sup> Damien Geradin, *A Proposed Test for Separating Pro-Competitive Conditional Rebates from Anti-Competitive Ones* (2008) <<http://dx.doi.org/10.2139/ssrn.1315292>> 34, 35.

<sup>151</sup> Intel (COMP/37–990) Commission Decision OJ C 227/13 para. 1002-1640.

analysis arguing that Intel had engaged in naked restrictions. According to the Commission, not only had Intel offered conditional rebates to producers of personal computers and laptops for the exclusive purchase of Intel processors, but it had also offered payments to the largest electronics retailer in Europe in return for their commitment to sell only personal computers and laptops that were manufactured using Intel processors, thereby reducing the contestable market.<sup>152</sup> It is somewhat unfortunate that the Commission chose to include this formalistic reasoning, but it is worth noting that, on appeal, the EU courts are likely to review the decision on this basis.<sup>153</sup>

It is questionable whether the General Court would consider an effects-based analysis including arguments based on the minimum efficient scale on the relevant market in an early entry agreement scenario. It may just reiterate the relevant case law and apply the formalistic approach instead. From a dominant brand company's perspective, it is therefore more likely to infringe Art. 102 TFEU because its conduct only needs to be capable of leading to anticompetitive foreclosure.

### **3.3.2. Restriction of choice**

In addition to the foreclosing effect on competing brand companies and subsequent generic companies, a single branding agreement also restricts the 'freedom of choice' of the generic company that entered into the early entry agreement. Due to the single branding obligation, the generic company is no longer allowed to choose freely which generic drugs it wants to produce and market.

However, one should keep in mind that every contract restricts the freedom of choice of the contracting parties. It needs to be established at what point a contractual restriction of choice turns into an anticompetitive restriction. This is particularly important in the present case, where the contractual restriction in the form of a single branding obligation is entered into by the generic company and the brand company as a patent owner prior to patent expiry. As has already been

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<sup>152</sup> Ibid. para 580, 581.

<sup>153</sup> Ezrachi (n 113),216; The European Commission also noted that the Guidance Paper is technically not applicable as the investigated events took place prior to the Guidance Paper.

mentioned above, the existence of an intellectual property right does not constitute an abuse itself but, at the same time, the exercise of the right is not automatically exempt from antitrust scrutiny. The appropriate balance has to be struck between the interest in protection of the intellectual property right and the interest of protecting free competition.<sup>154</sup> The patent owner can generally exclude others from making, using or selling his invention. The patent owner also has the right to enforce the patent right against infringement. These rights are at the core of the patent right.<sup>155</sup> If the patent owner has the right to exclude potential competitors and to enforce the patent against an infringement, it is logical that it should be within the general scope of the patent for the patent owner to grant a third party the right to make, use or sell the invention to a another party. It is also accepted that this license is granted on exclusive terms and can be restricted by the patent owner in territorial terms. Yet, post-patent expiry, this assessment ought to change, similarly to the above discussion relating to the anticompetitive foreclosure.

Over the past few decades, the European Commission as well as the EU courts have nonetheless repeatedly referred to the ‘freedom of choice’ or the ‘freedom to choose’ in their decisions and judgments concerning the infringement of Art. 102 TFEU, largely concerning the choice of trading partners.<sup>156</sup> Regarding the type of abuse, the freedom of choice has been, not surprisingly, often addressed in cases dealing with rebates and single branding agreements.<sup>157</sup> The restriction of this freedom suffices to constitute the requirements for showing an exclusionary

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<sup>154</sup> John Kallaugher, ‘Existence, exercise, and exceptional circumstances: The limited scope for a more economic approach to IP issues under Article 102 TFEU’ in Steven D Anderman and Ariel Ezrachi (eds), *Intellectual property and competition law: New frontiers* (Oxford University Press, Oxford, 2011) 136.

<sup>155</sup> *Ibid.* 137.

<sup>156</sup> Pinar Akman, ‘The role of ‘freedom’ in EU competition law’ (2013) forthcoming *Legal Studies* 1. 18.

<sup>157</sup> *Michelin v Commission* (n 59) where it was held that one has to consider whether the granting of certain discounts restricts or removes the buyer’s freedom of choice when determining whether a pricing practice is abusive. at [85]; this finding of the Court was subsequently restated in a number of cases dealing with rebates under Art 102 TFEU, Case T-228/97 *Irish Sugar plc v EC Commission* [1999] ECR II-2696. at [214]; Case T-203/01 *Manufacture française des pneumatiques Michelin v Commission* [2003] ECR II-4071. at [62]; Case C-95/04 P *British Airways plc v EC Commission* (n 110) at [67].

effect.<sup>158</sup> According to one commentator,<sup>159</sup> the leading case in terms “freedom of choice” as an important concept for competition policy is *France Telecom*,<sup>160</sup> where it was held by the ECJ in relation to the recoupment requirement in predatory pricing that:

*‘the lack of any possibility of recoupment of losses is not sufficient to prevent the undertaking concerned reinforcing its dominant position, in particular, following the withdrawal from the market of one or a number of its competitors, so that the degree of competition existing on the market, already weakened precisely because of the presence of the undertaking concerned, is further reduced and **customers suffer loss as a result of the limitation of the choices available to them.***<sup>161</sup>

In a recent judgment, the General Court expressly stated that exclusive agreements are:

*‘incompatible with the objective of undistorted competition within the [internal] market, because they are not based on an economic transaction which justifies this burden or benefit but are designed to **remove or restrict the purchaser’s freedom to choose his sources of supply and to deny producers access to the market.***<sup>162</sup>

In *Intel*, the European Commission has argued in the same vein. However, the European Commission did not only refer to the choice of the relevant trading partners but also emphasised the impact of single branding agreements on final consumers by stating that:

*‘products for which there was a consumer demand did not reach the market, or did not reach it at the time or in the way they would have in the absence of Intel’s conduct . As a result, customers were deprived of a choice which they would have otherwise had.’<sup>163</sup>*

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<sup>158</sup> Akman (n 156) 19.

<sup>159</sup> Paul Nihoul, *Freedom of Choice - The Emergence of a Powerful Concept in European Competition Law* (2012) <<http://dx.doi.org/10.2139/ssrn.2077694>>.

<sup>160</sup> Case C-202/07 P *France Télécom SA v. Commission of the European Communities* [2009] ECR I-2369.

<sup>161</sup> *Ibid.* para. 112 (emphasis added)

<sup>162</sup> *Tomra Systems ASA and Others v European Commission* (n 144) para. 209.

<sup>163</sup> *Intel* (n 151) para. 1679.

*'Intel was able to use the tool of conditional rebates that were capable of inducing loyalty and thereby limiting consumer choice and foreclosing the access of competitors to the market.'*<sup>164</sup>

The European Commission has also clarified in its Guidance on Art. 102 TFEU that, despite the fact that the concept of 'consumers' also encompasses intermediate producers and distributors, the focus in the analysis should be on final consumers, if the intermediate producers are actual or potential competitors of the dominant undertaking.<sup>165</sup> So in the case at hand, it is not sufficient to only show that the single branding agreement restricts the freedom of choice of the generic company but, in addition, it must be demonstrated that the choice of the final consumer is restricted, leading to likely consumer harm.

Finally, it is suggested that the "freedom of choice" is not only complementary to the analysis of efficiencies, but might even be prioritised above efficiencies by the ECJ. In *France Telecom*, the choice of consumers was discussed in relation to the recoupment requirement in predatory pricing cases. Whereas the lack of recoupment could lead to sustained low prices, which are beneficial to consumers, the harm could be considered in the reduction of choice following the elimination of competitors.<sup>166</sup>

If this should be true, then these considerations would support the EU courts' rather formalistic approach to exclusive dealing arrangements and would lead to an increased likelihood for the brand company to infringe Art. 102 TFEU by entering into early entry agreements beyond the life of the underlying patent. The single branding obligation in an early entry agreement restricts the generic company's ability to produce and sell drugs from other competing brand companies. This restriction prevents the generic company from offering a wider portfolio of drugs to the pharmacies and ultimately deprives the final consumer of an extended choice of drugs. Apart from a wider product range, the increased choice can also

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<sup>164</sup> Ibid. para. 1598.

<sup>165</sup> European Commission (n 71) Recital 19 fn 2.

<sup>166</sup> Nihoul (n 159) 27.

have a significant impact on price, depending on the substitutability between the different generic drugs.

### **3.4. Conclusion**

The analysis of early entry agreements under Art. 102 TFEU has shown that there is a possibility that brand companies entering into such arrangements could be found to have infringed Art. 102 TFEU. The likelihood of an infringement occurring – due to a single branding agreement being arranged prior to patent expiry and having the effect of deterring the entry of subsequent generic entrants that are no longer willing to enter the market “at their own risk” – depends on the acceptance of the theory that patents do not provide a *right to exclude* but a right to *try to exclude*. Post-patent expiry, the finding of an abuse is based on the European Commission’s decisional practice and the relevant case law. The brand company should have the special responsibility of not exploiting the advantages which it obtained during the period of patent protection after this patent has expired. Nonetheless, the finding of abuse should not be based on the formalistic approach adopted by the EU courts, which does not seem to be effectively challenged by the European Commission. Rather, it should take the form of an effects-based approach, showing the actual or potential foreclosing effects of the investigated conduct on a case-by-case basis.

## **4. Concluding remarks**

Early entry agreements are, in essence, a number of exclusive dealing agreements in different vertical relationships. The analysis under Art. 101 TFEU has shown that early entry agreements are likely to be block exempted from antitrust scrutiny as long as the parties to an early entry agreement do not exceed the relevant market share thresholds of 30 per cent. This result is not unexpected as early entry agreements have the clear potential for procompetitive effects. After all, the brand company allows a generic competitor to enter the market prior to patent expiry. Nonetheless, the anticompetitive potential that arises from exclusive sourcing obligations and single branding agreements should not be disregarded and should be scrutinised when the brand company is in a dominant position, if not before.

The Art. 102 TFEU analysis has shown that exclusive sourcing clauses in early entry agreements have the potential to foreclose the downstream market for input from upstream manufacturers for active pharmaceutical ingredients. The single branding clause of the agreements can have a foreclosing effect on the generic downstream market for competing brand companies as they are unable to compete for the entirety of the market. Additionally, early entry agreements have the potential to disincentive competing generic companies from challenging the validity of brand company patents due to the reduced profitability of “at their own risk” entry by generic companies. Single branding agreements can also reduce the generic company’s freedom of choice to sell generic drugs by competing brand companies which is ultimately likely to have adverse effects on consumer welfare. All of these types of conduct, with the exception of the “at their own risk” entry of generic competitors, are capable of – or likely to – lead to anticompetitive foreclosure only after the expiry of the underlying patent.

Despite this anticompetitive potential, the European Commission and the EU courts should refrain from a formalistic approach to early entry agreements. Finding an early entry agreement to have infringed Art. 102 TFEU in the absence of showing the actual foreclosure of the relevant market and the likely consumer harm arising from this, could lead to costly Type I errors – especially given the potential pro-competitive features of an early entry agreement. Furthermore, the divergent approach of the European Commission and the EU courts towards exclusive dealing arrangements creates legal and business uncertainty, which is particularly problematic for the commercial sector.<sup>167</sup> Such legal certainty is only likely to be achieved if the European Commission advocates for the effects-based approach set out in its Guidance and applies this approach in its decisional practice. This would give the EU courts the opportunity to change their formalistic view and to clarify the boundaries of Art. 102 TFEU.<sup>168</sup>

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<sup>167</sup> Ariel Ezrachi, ‘Form and effects based approaches: A challenging duality in the application of Art. 102 TFEU’ (2010) 2 *Concurrences*. 1.

<sup>168</sup> *Ibid.* 2.



## VI. CONCLUSION

This thesis has painted a picture of the current state of European pharmaceutical antitrust and offers recommendations for the prospective approach to a number of issues in the field. In doing so, the thesis ranges from an analysis of the *AstraZeneca* judgment, as the first fully litigated case in European pharmaceutical antitrust, to proposals for novel approaches to pay for delay settlements and early entry agreements. Finally it sets out areas of potential future research.

### 1. Findings and policy recommendations

This thesis started by analysing the General Court's *AstraZeneca* judgment in an attempt to derive general principles that could be used for future investigations into the European pharmaceutical sector. On the one hand, the analysis has shown that the *AstraZeneca* judgment unfortunately fails to provide general guidance for the pharmaceutical business sector in relation to market definition. Chapter II's application of the *AstraZeneca* market definition to a hypothetical market of antiepileptic drugs shows that the definition of the relevant market for Losec was highly fact-specific and should not be transposed to other markets. The General Court's fundamental assumption that doctors' prescribing inertia should be regarded as an exogenous factor to market definition is flawed. Not only has this assumption attracted criticism in the case of *AstraZeneca* itself, but the hypothetical analysis has also shown that doctors' prescribing inertia can constitute a key factor to consider when defining markets in an appropriate way. The analysis has provided empirical evidence that prescribing doctors and dispensing pharmacists will, for a number of reasons, tend to be cautious when switching their patients or customers to generic drugs. They can be wary of actual substitutability and thus related side-effects; want to avoid any confusion for their patients; and, in the case of pharmacists, can be faced with mistrust and suspicion and have to fight misconceptions about generic drugs. In the case of antiepileptic drugs in particular, the evidence provided shows that it is necessary to differentiate between 'drug switchability' and 'drug prescribability' because of the possible variance in the

generic drugs' bioequivalence, which can lead to severe adverse effects such as breakthrough seizures. This distinction depends on whether or not the patient has already been treated with an antiepileptic brand drug in the past. Doctors' inertia can therefore be seen as a rational behaviour that needs to be considered in order to define markets, so that the definition reflects the market realistically.

A robust market definition is essential not only for Art. 102 investigations but also in relation to the applicability of block exemption regulations to investigations under Art. 101 TFEU. Without a robust market definition, the likelihood of over-enforcement (Type I errors) increases, especially in the pharmaceutical sector which is highly regulated and heavily reliant on intellectual property rights. The European Commission should therefore not regard doctors' prescribing inertia as an exogenous factor to market definition and should refrain from drawing general principles from the market definition in *AstraZeneca* for future investigations in the European pharmaceutical sector. The definition in *AstraZeneca* is too fact-specific for these purposes.

On the other hand, the European Commission's and EU courts' dismissal of AstraZeneca's 'Walker Process argument' is an exemplar for careful comparative legal analysis, which is essential in pharmaceutical antitrust. It has been shown that the European Commission and the EU courts were right not to accept AstraZeneca's argument, that the very same conduct concerned would have been barred from antitrust scrutiny in the United States. The comparative analysis highlighted the fact that AstraZeneca's conduct would indeed not have met the required standards of proof to trigger a Walker Process claim, which would have put the conduct under antitrust scrutiny. But it would be wrong for the comparative analysis of this situation to end at this point. For a robust comparative analysis, one has to examine the underlying fundamental principles in the economic and legal context of the compared regimes and ask the question, whether the two regimes are actually comparable. Only following the answer to this question can one determine whether a certain type of conduct that is present in both regimes should actually be addressed by the same approach or not. In the case of *AstraZeneca*, the European

Commission and the EU courts opted for a European approach to the anticompetitive conduct of submitting misleading information to patent offices in an attempt to gain patents which the applicant is not entitled to. Following the analysis, it can be said that this approach is correct from a comparative perspective. The high US standards of proof for antitrust liability are caused by the private nature of the antitrust enforcement in relation to section 2 of the Sherman Act and the consequences of the trebling of damages. The US courts use these higher standards to reduce the number of successful private antitrust lawsuits as a corrective means to avoid over-deterrence. The absence of treble damages in Europe and the fact antitrust infringements are predominantly based on public enforcement by the European Commission, therefore justifies lower standards of proof in the European approach. The European Commission's approach to AstraZeneca's conduct should thus be seen as a "beacon" of comparative analysis and should be used as cornerstone for future investigations of conduct that is present in the United States and Europe.

With this consideration in mind, one would hope that the European Commission would take the same careful approach to other areas of pharmaceutical antitrust, particularly in relation to pay for delay settlements.

The analysis in chapter III has highlighted the fundamental differences between the US and European pharmaceutical drug approval litigation, which therein required the development of a European theory of harm. In contrast to the United States, brand companies in Europe cannot generally foreclose the market by paying off a single generic competitor. European pharmaceutical drug approval regulation does not prevent generic companies from entering the market based on the existing patent protection of the brand drug. Of course these generic entrants are likely to be exposed to patent infringement litigation, but entry is not foreclosed by a regulatory bottleneck, as is the case in the United States. However, the alternative theory of harm in chapter III shows that a pay for delay settlement can also lead to foreclosure in Europe, if the relevant market is conducive to foreclosure due to its actual characteristics and structure. The anticompetitive effect of a pay for delay settlement is therefore dependent on the economic context in which the

settlement takes place. If only one potential generic competitor exists, anticompetitive foreclosure is likely; however, if a large number of potential entrants are present, paying off a single entrant or even a few is unlikely to lead to foreclosure. In this case, generic entry would be imminent. In the latter example, it is difficult to see how the pay for delay settlement would cause anticompetitive effects.

For these reasons, this thesis calls for an effects-based approach to pay for delay settlements and develops a “structured effect-based” approach to these settlements under European competition law. Similar to the guidance provided for the lower courts by the US Supreme Court in *FTC v Actavis*, the proposed test avoids an examination of the validity of the underlying patent without disincentivising general patent settlements in the pharmaceutical sector. In addition, the proposed test takes into consideration the regulatory differences described in the previous paragraph and only regards pay for delay settlements as anticompetitive if, based on the market structure, they have the actual potential to cause anticompetitive foreclosure. Further advantages of this test include the fact that it enhances legal certainty and does not require any legislative change.

Legal certainty is enhanced as the test circumvents the most contentious and problematic issue – the probabilistic nature of patents and the need to determine their validity as part of the antitrust inquiry. Instead, the proposed test is a cost-based analysis into the economic gains received by the generic company as part of the pay for delay settlement. This test is beneficial for the competition authority, who should be comfortable in administering a cost-based analysis, as well as for the brand and generic company, because the test offers a brighter line than a potential inquiry into the validity of the underlying patent, whose outcome is often difficult to predict.

The applicability of the proposed test is also provided under the current European competition law regime. The EU courts’ effects-based approach in *Delimitis* can be regarded as a structured inquiry into anticompetitive effects. The proposed test is therefore to be seen as an extension to the rationale of *Delimitis*. The EU courts have also previously recognised, in relation to information exchange

in RPM cases, that certain proxies might be used as evidence of effects. A truncated effects-based analysis is therefore not unheard of. The proposed test combines these two features. The European Commission should thus be able to issue guidelines for the pharmaceutical sector which set out the approach to pay for delay settlements and outline the facts considered in such an analysis.

Unfortunately, the European Commission has since reverted back to its old *modus operandi*, despite previously proclaiming an effects-based approach in its pharmaceutical sector inquiry. In its first ever investigation into a European pay for delay settlement case, involving Lundbeck and a number of generic competitors, the European Commission found a ‘restriction by object’. This finding of course increases the European Commission’s likelihood of success on appeal, in particular because of the European courts’ reluctance to apply an effects-based approach in European competition law. However, the question that remains is whether or not the European Commission and the European Commission’s legal service team should focus predominantly on success in litigation<sup>1</sup> in front of the EU courts or whether it should rather aim to convince the EU courts to accept a more effects-based approach, as has been proclaimed by the European Commission since 2004.

In addition to pay for delay settlements, this thesis has also addressed early entry agreements. For the first time, a European theory of harm has been developed for such agreements and has subsequently been put under detailed European competition law scrutiny. The general rationale behind this novel theory of harm is that the brand company ‘teams up’ with an early generic entrant in order to create a ‘pet competitor’. Given the restrictive nature of early entry agreements and the fact that their duration proceeds in many cases beyond the expiry date of the brand company’s patent, this provides the brand company with the opportunity to control its first generic competitor. This control allows the brand company to maintain generic prices above the competitive level and, fundamentally, has affords it the

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<sup>1</sup> The European Commission’s legal service seems to pride itself with a high success rate in litigation in front of the EU courts, see European Commission Legal Service, ‘Presentation of the legal service and its activities’ (April 2013) <[http://ec.europa.eu/dgs/legal\\_service/index\\_en.htm](http://ec.europa.eu/dgs/legal_service/index_en.htm)> p.19.

ability to distort the competitive process post patent expiry, as the brand company can exploit the significant first-mover advantage that the generic entrant has attained due to the early entry. Such control and exploitation of the generic first-mover advantage is only achievable if subsequent entry is deterred or delayed.

The focus of the competition law analysis, particularly in relation to the potential abuse of the brand company's dominant position, is therefore centred on the exclusive nature of early entry agreements and their impact on the relevant market post patent expiry. In a detailed legal analysis, the final chapter in this thesis determines the likely approach to be adopted by the European Commission and the EU courts in relation to exclusive sourcing agreements and single branding agreements (both a common feature of early entry agreements according to the pharmaceutical sector inquiry). The chapter derives evidence from a number of sources, including previous decisional practice, guidelines and previous case law. In relation to both exclusive sourcing agreements and single branding agreements, the European Commission is likely to opt for a more form-based – rather than a more effects-based – approach. Throughout the chapter, this approach is critiqued and an argument is put forward in favour of a more effects-based analysis. Just as in the case of pay for delay settlements, it is vital to strike the right balance between short-term and long-term efficiencies. This is even more so the case with early entry agreements, which can clearly have pro-competitive effects. After all, these agreements allow generic entry prior to the brand company's patent expiry, which provides the consumer with a wider and cheaper choice of drugs.

These pro-competitive effects have generally been highlighted by the Art. 101 analysis which shows that early entry agreements would tend to be block-exempted as long as the parties meet the market share threshold. The analysis of the applicability of the relevant Block Exemption Regulation once again emphasises the need for a robust market definition, which has already been addressed in chapter II. The market definition determines – to a large extent – whether the parties to an early entry agreement are block-exempted or not. For the sake of completeness, it should be reiterated that this thesis does not analyse the 'grey area' for early entry agreements; namely, agreements which fall just outside those

thresholds but where the brand company is nonetheless short of being in a dominant position. Early entry agreements have too many variables to undertake an effective analysis of this, and the pharmaceutical sector inquiry provides insufficient information and details.

In terms of policy recommendations, early entry agreements definitely warrant antitrust scrutiny. Once the brand company is in a dominant position, early entry agreements can have significant anticompetitive potential, as they keep the generic price above the competitive level and restrict choice for the consumer. However, because of the potential pro-competitive effects that can arise from early entry agreements, the European Commission should adopt an effects-based approach and should refrain from a form-based analysis. Finally, there is no need to develop a novel type of abuse. The novel theory of harm, based on the creation of a pet competitor, can be remedied by ensuring that the brand company cannot deter or delay subsequent entry by means of exclusivity arrangements with the early generic entrant post patent expiry.

Fundamentally, the aim of pharmaceutical antitrust must be to strike of the right balance between dynamic and static efficiencies. In a highly regulated sector such as the pharmaceutical sector, this is only possible if the actual economic and legal circumstances are considered within the investigated conduct. Ultimately, this requires an effects-based approach.

## **2. Future research**

It is envisioned that a number of potential research projects could follow from this thesis. As has been stated in the introduction, the aim of this thesis has been to adopt a “macro approach” to pay for delay settlements and early entry agreements in the European context. This has created the opportunity to: develop two general theories of harm, develop a novel test for pay for delay settlements, and conduct a general competition law analysis for early entry agreements. To some extent, this has been possible because of the stated limitations, namely the exclusion of

pharmaceutical pricing and reimbursement regulations, which are within the competences of the relevant European Member State.

One potential future research project applies the general principles and tests on a micro-level to individual Member States, thereby relaxing the initial limitations. The introduction of national pricing and reimbursement policies can have a significant impact on the anticompetitive potential that might arise from pay for delay settlements and early entry agreements in particular. For example, some Member States have a free pricing policy for drugs whereas others impose price regulation.<sup>2</sup> A free pricing policy, however, does not necessarily give the pharmaceutical companies free reign in their pricing behaviour. The drug price can be indirectly influenced by the reimbursement price, which determines how much a third party payer like an insurance company will pay for the drug. The reimbursement price is again determined through different methods. In addition to this already complex structure, generic drug policies can once again differ across the Member States. Most Member States have price controls in place for generic drugs sold at the manufacturer, wholesale or pharmacy level; yet the methodology is different. Although internal reference pricing is the most common procedure, whereby the generic price is compared to the prices of identical or similar drugs in the same country, a number of Member States also employ what is regarded “generic price linkage”.<sup>3</sup> This linkage can require generic drugs to be priced at a certain percentage lower than the brand drug. The actual percentage again depends on the policy of the relevant Member States. This mere enumeration of possible variables that can have an impact on potential effects, subsequent entry and especially the final drug price for consumers, once again confirms the need to exclude these kinds of regulations from the analyses in this thesis. However, it also showcases the potential for a number of country-specific case studies in relation

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<sup>2</sup> Sabine Vogler, *PPRI report: pharmaceutical pricing and reimbursement information* (Gesundheit Österreich GmbH Geschäftsbereich ÖBIG, Vienna, 2008) 59.

<sup>3</sup> Sabine Vogler, ‘The impact of pharmaceutical pricing and reimbursement policies on generic uptake: implementation of policy options on generics in 29 European countries - an overview’ (2012) 1 *Generics and Biosimilars Initiative Journal* 44, 46.



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the anticompetitive potential of pay for delay settlements and early entry agreements in a given Member State.

Another potential research project would investigate the multimarket contact between a brand company and a generic company. In the pharmaceutical sector inquiry, it has been stated that a large number of originator companies have preferred generic companies with whom they repeatedly work together. Mapping the repeated business contacts of the same brand and generic company could enable one to extend the developed European theory of harm to a scenario where the early generic entry in one market could be used as a form of value transfer in return for the delay of entry in another market. However, for this to be feasible, one would have to identify the parties to the pay for delay settlements that are referred to in the pharmaceutical sector inquiry and then find agreements between the same parties in other Member States that involve a generic entry decision. At an earlier stage of my doctoral research I attempted to gain access to the data set on which the pharmaceutical sector inquiry was based; however, this attempt proved to be unsuccessful. This research idea has therefore been postponed for post-doctoral research.

## APPENDIX

This appendix explains in detail the relevant approval procedures for brand drugs and generic drugs. Section 1 deals with the approval procedures in the United States and section 2 deals with the approval procedures in Europe.

### 1. The US drug approval procedure

Every new drug that a pharmaceutical company wishes to market in the United States has to be approved by the US Food and Drug Administration (FDA). Depending on the type of drug for which approval is sought, a specific regulatory procedure is in place. Any drug whose composition is not generally recognised among experts – namely, experts who are qualified by scientific training and experienced in evaluating the safety and effectiveness of drugs – is regarded as a new drug.<sup>1</sup> This is the case for drugs that include new active ingredients, are formulated differently, have a new route of delivery, or are intended to be used for purposes which have yet to be approved by the FDA. For these kinds of drugs, the approval process for “new drugs” has to be followed. In contrast to new drugs, generic drugs have to follow the “abbreviated new drug application” process. This is a shorter application process for drugs that are not new but, rather, equivalent to an approved drug which has therefore already been examined by the FDA and has been declared safe and effective.

#### 1.1. Approval of a new drug

In simple terms, the approval process for new drugs consists of 4 stages: (i) pre-clinical testing, (ii) an investigational new drug application, which is followed by (iii) clinical testing in 3 phases and, finally, (iv) submitting a new drug application which, if successful, certifies the safety and efficacy of the drug.

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<sup>1</sup> 21 CFR §321 (p)(1).

### 1.1.1. Investigational new drug application

Once an innovating pharmaceutical drugs company (brand company) has discovered a potentially new drug in pre-clinical trials, the investigational new drug application (IND) is the first necessary step in the drug approval process. Without having been granted the IND, the brand company that is sponsoring the development of the drug cannot enter into the clinical testing stage. During the process of evaluating the IND, the pharmaceutical company has to prove that the active ingredient is reasonably safe for testing on humans. This is usually established by means of animal testing. These pre-clinical tests on animals determine the pharmacological activity of the new molecules and their toxicity potential in animals. In addition to this data, an IND application must also include information about the manufacturing process of the drug, such as: the composition of the drug, information about the pharmaceutical company itself, its researchers and detailed protocols about the design and the execution of the clinical tests.<sup>2</sup> Following the submission of a complete IND application, the pharmaceutical company must wait 30 days before it can start the clinical testing phase. Within this timeframe, the FDA has the opportunity to review the application and establish whether the risk to humans – which would be thoroughly analysed in the clinical testing phase – would not be unreasonable high.<sup>3</sup> If this time period concludes without the submission of a statement of objections by the FDA, the pharmaceutical company can proceed to the clinical trials stage.

### 1.1.2. New drug application

The final hurdle in the approval process for a drug arrives at the new drug application (NDA) stage. The essential part of this application concerns the results that the company obtains from clinical testing, which consists of three phases:

- (1) Phase 1: *This includes the initial introduction of an investigational new drug into humans. Phase 1 studies are typically closely*

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<sup>2</sup> 21 CFR §312.23.

<sup>3</sup> 21 CFR §312.20.

monitored and may be conducted in patients or normal volunteer subjects. These studies are designed to determine the metabolism and pharmacologic actions of the drug in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness. During Phase 1, sufficient information about the drug's pharmacokinetics and pharmacological effects should be obtained to permit the design of well-controlled, scientifically valid, Phase 2 studies. The total number of subjects and patients included in Phase 1 studies varies with the drug, but is generally in the range of 20 to 80'.<sup>4</sup>

- (2) Phase 2: 'Phase 2 includes the controlled clinical studies conducted to evaluate the effectiveness of the drug for a particular indication or indications in patients with the disease or condition under study and to determine the common short-term side effects and risks associated with the drug. Phase 2 studies are typically well controlled, closely monitored, and conducted in a relatively small number of patients, usually involving no more than several hundred subjects'.<sup>5</sup>
- (3) Phase 3: 'Phase 3 studies are expanded controlled and uncontrolled trials. They are performed after preliminary evidence suggesting effectiveness of the drug has been obtained, and are intended to gather the additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug and to provide an adequate basis for physician labelling. Phase 3 studies usually include from several hundred to several thousand subjects'.<sup>6</sup>

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<sup>4</sup> 21 CFR §312.21.

<sup>5</sup> Ibid.

<sup>6</sup> Ibid.

Having filed all information about these clinical studies, as well as the other content required for a successful application set out in 21 CFR §314.50, the FDA is then able to evaluate the safety and effectiveness of the drug whose approval is sought.

In addition to the submission of an NDA, the applying brand company has to file certain patent information with the FDA. All of the patent information that has been submitted must be gathered and consolidated into a publication called ‘Approved Drug Products with Therapeutic Equivalence Evaluations’, more commonly known as ‘the Orange Book’. In accordance with this requirement, the pharmaceutical company *‘shall submit information on each patent that claims the drug or a method of using the drug that is the subject of the new drug application or amendment or supplement to it and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug product’*.<sup>7</sup> This Orange Book requirement can be seen as the linkage of patent protection with the safety and effectiveness of the relevant drug. This requirement is vital for the applying pharmaceutical company, as well as the FDA itself with regard to the application and the potential future approval of similar drugs by other pharmaceutical companies or generic versions of the same drug.<sup>8</sup> Nonetheless, the FDA does not examine the submitted patents for their conformity with the Orange Book filing requirements. It has repeatedly stated that it lacks the resources and expertise that are necessary for reviewing patent matters.<sup>9</sup> The FDA considers itself to be in a mere ministerial role and regards private patent litigation as *‘the appropriate mechanism for the resolution of disputes about the scope and the validity of patents’*.<sup>10</sup> Consequently, following a “Final Rules Changes” in the Federal Register, the FDA refused to propose an administrative process for challenging patent listings and for seeking the removal of a patent from the Orange Book.<sup>11</sup>

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<sup>7</sup> 21 CFR §314.53 (b).

<sup>8</sup> See *infra* 1.2.2 for further discussion.

<sup>9</sup> 59 Fed. Reg. 50338, 50343 (Oct. 3, 1994); 68 Fed. Reg. 36676, 36683 (June 18, 2003).

<sup>10</sup> *Ibid.*

<sup>11</sup> 68 Fed. Reg. 36676, 36683 (June 18, 2003).

### 1.1.3. Patent term restoration

The possibility of patent term restoration for pharmaceutical patents was introduced by Congress in 1984 as part of the Drug Price Competition and Patent Restoration Act of 1984, more commonly known as the Hatch Waxman Act. The aim of the Act was to mitigate the adverse effects of the lengthy drug approval process of the FDA. These adverse effects are caused by the fact that two different regulatory agencies are involved in the pharmaceutical sector. On the one hand, the United States Patent and Trademark Office (USPTO) grants pharmaceutical patents that secure the intellectual property rights of companies. To be able to market the patent-protected drug, the pharmaceutical company has to follow the aforementioned approval process. During this process, the “patent clock” is already ticking as the pharmaceutical company typically applies for a patent with the USPTO before the clinical testing phase, at the same time as it applies for the IND with the FDA.<sup>12</sup> The normal patent term lasts for 20 years from the date on which the application for the patent is filed with the USPTO.<sup>13</sup> As this application takes place prior to the IND application with the FDA, the effectiveness of patent protection is significantly reduced in the pharmaceutical industry compared to other industries. Empirical research has shown that the effective patent life in the pharmaceutical sector is, on average, 11-12 years.<sup>14</sup> The pharmaceutical company holding the patent can therefore apply for a patent extension. Such an extension can be granted for up to 5 years,<sup>15</sup> provided that the overall patent protection period does not exceed 14 years in total.<sup>16</sup> The application for a patent extension must be filed with the USPTO within 60 days of the date at which the product is approved by the FDA. *‘Usually, the approval date is the mailing date of the FDA letter granting*

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<sup>12</sup> Federal Trade Commission, *To promote innovation: The proper balance of competition and patent law and policy*. A report by the Federal Trade Commission (2003) <<http://www.ftc.gov/os/2003/10/innovationrpt.pdf>> chapter 3, 6.

<sup>13</sup> 35 U.S.C. § 156.

<sup>14</sup> Henry Grabowski, ‘Patents, innovation and access to new pharmaceuticals’ (2002) 5 *Journal of International Economic Law* 849, 852,853; Henry G Grabowski and Margaret Kyle, ‘Generic competition and market exclusivity periods in pharmaceuticals’ (2007) 28 *Managerial & Decision Economics* 491.

<sup>15</sup> 35 U.S.C. § 156 (g)(6).

<sup>16</sup> 35 U.S.C. § 156 (c)(3).

*permission for commercial marketing or use*.<sup>17</sup> This application is then referred to the FDA who will determine the regulatory review period which will be published in the Federal Register. This determination becomes final after a period of 180 days. Following notice of the final determination, the USPTO will proceed to calculate the actual patent term extension and will then issue it to the applicant.<sup>18</sup>

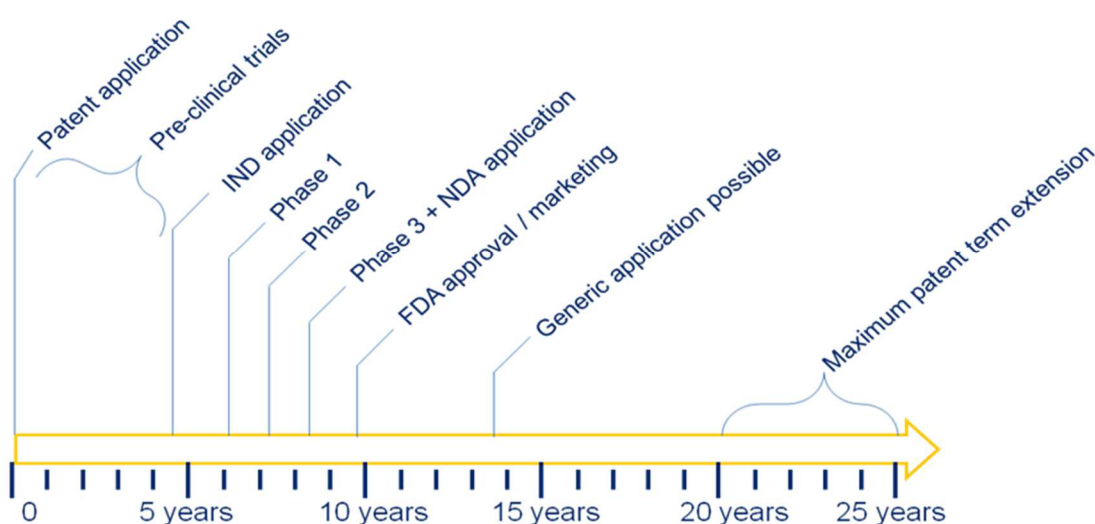


Fig. 11: US drug approval process

## 1.2. Approval of a generic drug

A generic company intending to produce and market a generic version of a drug has to seek FDA approval for this drug, just as in the case of brand companies. Prior to the Hatch Waxman Act, every generic applicant was required to fulfil the same conditions for an application as the pharmaceutical company that had invented the drug. Generic companies therefore had to satisfy the same clinical test that had already been overcome by the brand company. As generic companies struggled to meet these requirements, it created a problem whereby only a few generic drugs were available in the marketplace, even though the patent protection for around

<sup>17</sup> Karin L Tyson, 'The Role of the Patent and Trademark Office Under 35 U.S.C. Section 156' (1999) 54 Food & Drug Law Journal 205, 206.

<sup>18</sup> Ibid. 205.

150 drugs had expired at that time.<sup>19</sup> During deliberations in the US Senate, it was estimated that the enactment of legislation to facilitate generic entry would lead to significant savings for federal as well as local governments, particularly given they had spent ‘*approximately 2.4 Billion US dollars for drugs in the MEDICAID program, and in veteran and military hospitals*’ during the fiscal year 1983 alone.<sup>20</sup> Congress passed the Hatch Waxman Act in 1984 in an attempt to facilitate generic entry and to realise these cost savings. In doing so, Congress broadened the FDA’s remit beyond mere safety and effectiveness considerations to also encompass economic considerations. In light of this, the following section describes the procedure of an ‘abbreviated new drug application’ (ANDA) and sets out the differences between this and a ‘new drug application’ (NDA) which has to be filed with the FDA by every innovating company in order to be granted approval for their new drug.

### **1.2.1. Abbreviated new drug application (ANDA)**

An abbreviated new drug application must contain: (1) ‘a full list of the articles used as components of such drug’, (2) ‘a full statement of the composition of such drug’, (3) ‘a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug’, (4) ‘samples of such drug and of the articles used as components thereof as the Secretary may require’, and (5) ‘specimens of the labelling proposed to be used for such drug.’<sup>21</sup> These are the same requirements as for an NDA.<sup>22</sup> However, the main difference is that an ANDA does not require a full report to be filed showing ‘whether or not such drug is safe for use and whether such drug is effective in use’ and supported by clinical trials.<sup>23</sup> Instead, the generic applicant has to show that its drug is the ‘same’ as an existing ‘listed drug’; meaning a drug which has already been approved by the FDA following a NDA. This ‘sameness’ requirement has to be proven through different means. Information has to be provided that shows ‘*that the route of administration,*

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<sup>19</sup> House Report on the Drug Price Competition and Patent Restoration Act, H.R. REP. 98-857(I), 1984 U.S.C.C.A.N. 2647, 2652.

<sup>20</sup> Ibid.

<sup>21</sup> 21 U.S.C. §355 (b)(1)(B)-(F).

<sup>22</sup> 21 U.S.C. §355 (j)(2)(A) vi) referring to 21 U.S.C. §355 (b)(1)(B)-(F).

<sup>23</sup> 21 U.S.C. §355 (b)(1)(A)



*dosage form, and strength of the drug product are the same as those of the reference listed drug*.<sup>24</sup> *'An ANDA may not be considered for a condition of use that has not been previously approved for the listed drug'*.<sup>25</sup> Additionally, the generic applicant also has to show that its generic product is 'bioequivalent' to the listed drug. This means that *'the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses'*.<sup>26</sup> For this purpose, the generic company can rely on the results of the clinical trials filed by the brand companies for their NDA.

However, the possibility of referring to the clinical data that the brand company had to file with the FDA is limited by data protection provisions. These provisions not only prevent the FDA from granting generic applications but also from assessing them. Generally speaking, the period of data exclusivity is five years. During this period, an ANDA cannot even be submitted to the FDA,<sup>27</sup> as the generic company cannot rely on the clinical data from the brand company. The effect of this is that the grant of a generic application is, on average, delayed by 6.5 years, as the FDA needs an average of 18 months to approve such an application.<sup>28</sup> This exclusivity period can be reduced to four years if the ANDA contains what is called a Paragraph IV certification, which will be discussed below.<sup>29</sup> A third possibility gives the brand company three years of market exclusivity. This is applicable to cases where the FDA has only approved a new type of use or indication for a drug that has already been granted approval. The main difference between this and the other two types of data exclusivity is that it does not preclude generic companies from submitting an ANDA during this period. They are free to seek market authorisation

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<sup>24</sup> 21 U.S.C. §355 (j)(2)(A); 21 C.F.R. §314.94(a)6.

<sup>25</sup> House Report (n 19) 2654.

<sup>26</sup> 21 U.S.C. §355 (j)(8)(B)(i); 21 C.F.R. §320.1(e).

<sup>27</sup> 21 U.S.C. §355 (j)(5)(F)(ii).

<sup>28</sup> Judit R Sanjuan, 'U.S and E.U Protection of Pharmaceutical Test Data' (2006) <<http://www.cptech.org/publications/CPTechDPNo1TestData.pdf>> 6.

<sup>29</sup> 21 U.S.C. §355 (j)(5)(F)(ii).

during this period and enter the market as soon as the period of market exclusivity expires.<sup>30</sup>

### 1.2.2. Certification of brand companies

As an additional requirement for a successful ANDA, the generic company has to notify the brand company, whose drug it wishes to copy. Subject of these certifications are all patents that claim the listed drug, which was previously approved by the FDA. During the process of an NDA, the FDA endeavours to list every patent that is filed with the drug application and that claims the drug. Only patents that are listed in the abovementioned Orange Book are subject to such a certification. The FDA's regulations provide four different types of certifications:<sup>31</sup>

- (1) that no patent has been filed with the FDA that claims the drug (Paragraph I certification);
- (2) that the relevant patent has expired (Paragraph II certification);
- (3) that the generic company is seeking with its ANDA approval by the FDA for the time after the relevant patent has expired (Paragraph III certification); and
- (4) that the patent which claims the drug of the innovator company 'is invalid or will not be infringed by the manufacture , use, or sale of the new drug for which the application is submitted',<sup>32</sup> (Paragraph IV certification).

The first three certifications are generally not problematic as they claim that either no patent is listed with the FDA or that the patent has already expired or will not be infringed because the generic company is waiting for the patent to expire before starting with the marketing and sale of the generic version of that product.<sup>33</sup>

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<sup>30</sup> Ibid. 7.

<sup>31</sup> 21 U.S.C. §355 (j)(2)(A)(vii).

<sup>32</sup> 21 U.S.C. §355 (j)(2)(A)(vii)(IV).

<sup>33</sup> Elizabeth S Weiswasser and Danzis Scott D. 'The Hatch-Waxman Act: History, Structure, and Legacy' (2003) 71 Antitrust Law Journal 585, 600.

However, the situation is different with Paragraph IV certifications. In these cases, the generic applicant is of the opinion that a patent which is listed with the FDA is either invalid – and thus wrongfully listed – or simply not infringed by the drug product for which the generic company is seeking FDA approval. Without such a notification, the brand company would only become aware of a generic version of its drug product after the beginning of the generic marketing and sale. Therefore, it had been anticipated that the Paragraph IV certification should be provided to the brand company simultaneously to the submission of the ANDA to the FDA.<sup>34</sup> The FDA regulations, however, state that the paragraph IV certification has to be submitted *'not later than 20 days after the date of the postmark on the notice with which the FDA informs the applicant that the application has been filed'*.<sup>35</sup> This intertwines the generic drug approval with the validity of patents that cover the already approved brand drug. The independence of both the USPTO's process of awarding patents and the FDA's drug approval and market authorisation is still maintained, but the Hatch Waxman Act can be regarded as an interface linking the two different events in the case of generic drug approval, by means of the previously explained Orange Book requirement.

### **1.2.3. Approval of an ANDA**

The date on which the notification has been submitted to the brand company also triggers a period of 45 days during which the brand company is entitled to bring an action for patent infringement against the ANDA applicant.<sup>36</sup> In case this period has expired without filing for an action for patent infringement, the approval of the ANDA shall be effective from that point onwards. In contrast, the approval of the FDA will be automatically postponed by 30 months, if the brand company has filed a lawsuit against the generic company.<sup>37</sup> During this period of time, the patent challenge ought to be resolved through litigation in front of the court. Following this postponement, the FDA approval will be effective from the date at which: (1)

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<sup>34</sup> House Report (n 19) 2657.

<sup>35</sup> 21 U.S.C. §355 (j)(2)(B)(ii)(I).

<sup>36</sup> 21 U.S.C. §355 (j)(5)(B)(iii).

<sup>37</sup> Ibid.

the patent expires; (2) the court decides on the non-infringement or patent invalidity in the patent litigation; or (3) the thirty months from the date of notification have expired,<sup>38</sup> whichever occurs first.

### 1.1.1 180-day generic exclusivity

The Hatch Waxman Act grants a period of generic exclusivity to the first generic company that challenges the validity of a pharmaceutical brand patent. The first generic applicant who files an ANDA that includes a Paragraph IV certification is given a 180-day period of generic exclusivity.<sup>39</sup> This means that every subsequent generic applicant that files an ANDA with the FDA for the same drug will not be approved until this period has expired. *'The 180-day exclusivity period was included in the legislation to encourage generic companies to invest in the required product testing and to cover expensive legal challenges to innovator products'*.<sup>40</sup> Without such an incentive, it would be less likely that generic companies would take the risk of challenging the validity of patents, as patent infringement lawsuits are costly and – in case of success – beneficial to every other generic company that intends to enter. The patent is not just invalidated “inter partes” but rather “erga omnes”, meaning that other generic companies can free-ride on the first-filing generic company’s success in patent litigation.<sup>41</sup>

Yet it is important to determine at what stage of patent litigation this generic exclusivity period is rewarded. While initially this bounty was only awarded following a successful patent infringement litigation that had been triggered by a Paragraph IV certification, since 1998 the generic challenger has been eligible for the bounty *'provided that it does not lose the patent suit, even if it never actually wins the patent litigation'*.<sup>42</sup> This change in the interpretation of the Hatch Waxman

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<sup>38</sup> Federal Trade Commission, *Generic drug entry prior to patent expiration: A FTC study* (2002) <<http://www.ftc.gov/reports/generic-drug-entry-prior-patent-expiration-ftc-study>> 41.

<sup>39</sup> 21 U.S.C. §355 (j)(5)(B)(iv).

<sup>40</sup> Robin J Strongin, *Hatch-Waxman, generics, and patents: Balancing prescription drug innovation, competition, and affordability* (2002) NHPF Background paper <[www.nhpf.org/pdfs\\_bp/BP\\_HatchWaxman\\_6-02.pdf](http://www.nhpf.org/pdfs_bp/BP_HatchWaxman_6-02.pdf)> 11.

<sup>41</sup> C. S Hemphill and Mark A Lemley, ‘Earning Exclusivity: Generic Drug Incentives and the Hatch-Waxman Act’ (2011) 77 *Antitrust Law Journal* 947, 953.

<sup>42</sup> *Ibid.* 954, 955.

Act by the FDA opened the doors for pay for delay settlements. In 2003, the Hatch Waxman Act was amended by the Medicare Modernization Act (MMA),<sup>43</sup> in order to rectify a number of problematic provisions including the exclusivity award for the generic first-filer. With enactment of the MMA, forfeiture rules were introduced under which the first-filing generic applicant may now lose the generic exclusivity it has been awarded.<sup>44</sup> Under these provisions, a later-filing generic applicant can force the first-filing generic applicant to start using its generic exclusivity or otherwise face losing it. In order for these provisions to apply, the later-filing generic applicant has to win a patent infringement lawsuit of its own – not only at the district court level but also in front of an appellate court. If the later-filing generic succeeds in doing this, the generic exclusivity has to be triggered within 75 days. Not only has this process been described as very time-consuming, but also as very difficult to achieve, as it requires the later-filer to be sued for patent infringement by the brand company. If the brand company were to decide not to file a suit against the later-filer, the generic company is stuck behind the first-filing ANDA and cannot gain FDA approval.<sup>45</sup> The only other possible option would be to file for declaratory judgment which would trigger the same mechanism.<sup>46</sup>

## 2. The European drug approval procedure

The drug approval procedure in Europe is similar to that observed in the United States, but with some significant differences which will be addressed in this section. The procedure in Europe is not as straightforward as in the United States. Market authorisation for a drug can be obtained via different routes. A pharmaceutical company can apply for market authorisation by using the *centralised procedure*, also referred to as the Community authorisation. On a national level, the company can also utilise the *mutual recognition procedure* or the *decentralised procedure*. For the sake of simplicity and understanding, this section focuses on the centralised

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<sup>43</sup> *Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat 2066.*

<sup>44</sup> 21 U.S.C. § 355(j)(5)(D).

<sup>45</sup> Hemphill and Lemley (n 41) 964.

<sup>46</sup> *Ibid.*

procedure and briefly addresses the mutual recognition procedure and the decentralised procedure separately at the end of the section.

## 2.1 Approval of a new drug

Similarly to the United States, the approval process for a new drug consists of 4 stages: (i) pre-clinical testing, (ii) a request for clinical trial authorisation, followed by (iii) clinical trials which lead to (iv) an application for marketing authorisation, which if success certifies the safety and efficacy of the drug.

### 2.1.1 Request for a clinical trial authorisation

In contrast to the US procedure, the request for clinical trial authorisation has to be filed with the Ethics Committee in the European Member State in which the clinical trials shall take place.<sup>47</sup> Based on the information provided in this request, the Ethics Committee of the relevant Member State has to come to the *'conclusion that the anticipated therapeutic and public health benefits justify the risks [of clinical trials] and may be continued only if compliance with this requirement is permanently monitored'*.<sup>48</sup> The time-frame in which to make this decision is 30 days from the day the request was submitted.<sup>49</sup> The requirements for the conduct of clinical trials in Europe are set out in the 'Clinical Trial Directive',<sup>50</sup> and are formalised in the 'Good Clinical Practice Directive'.<sup>51</sup> Based on this secondary legislation, Member States have set up clinical trials that are very similar to the aforementioned trials in the United States, as described in detail above.<sup>52</sup>

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<sup>47</sup> Council Directive 2001/20/EC of the European Parliament and of the Council on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use [2001] OJ L 121/34, Art.9 (2).

<sup>48</sup> Ibid. Art.3 (2) (a).

<sup>49</sup> Ibid. Art.9 (4).

<sup>50</sup> Ibid.

<sup>51</sup> Commission Directive 2005/28/EC laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorisation of the manufacturing or importation of such products [2005] OJ L 91/13

<sup>52</sup> The author therefore refrains from setting out the clinical trials in a European Member State. See NHS, 'Clinical trials and medical research - Phases of trials' <<http://www.nhs.uk/Conditions/Clinical-trials/Pages/Phasesoftrials.aspx>>.

### 2.1.2 Market authorisation application following the centralised procedure

Following the clinical trials, an application for market authorisation can then be filed with the European Medicines Agency (EMA). Within the EMA, the actual decision on market authorisation applications is made by the Committee for Medicinal Products for Human Use (CHMP), which draws up its opinion on why it chooses to grant or refuse market authorisation.<sup>53</sup> The CHMP itself must ensure that this opinion is given within 210 days of the receipt of a valid application.<sup>54</sup> A valid application has to include *'the name and the qualitative and quantitative particulars of all the constituents of the medicinal product, the manufacturing method, therapeutic indications, contra-indications and side-effects, posology, pharmaceutical form, method and route of administration, expected shelf life, reasons for precautionary and safety measures during storage and administration of the medicinal product and disposal of waste, the risk to the environment, the results of pharmaceutical, pre-clinical tests and clinical trials, a summary of the product characteristics and a mock-up of the packaging together with a package leaflet'*.<sup>55</sup> In the event of an application being rejected, the CHMP must notify the applicant of the reasons for the rejection and has to give the applicant the possibility to rectify its application within 15 days. Having received the amended application, the CHMP has a further 60 days to re-examine the application.<sup>56</sup> The opinion of the CHMP is then referred to the European Commission who will adopt the final decision on the market authorisation after consulting the Member States and the applicant.<sup>57</sup>

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<sup>53</sup> Council Regulation (EC) No. 726/2004 of the European parliament and of the Council laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency [2004] OJ L 136, Art. 55, 56 (1)(a).

<sup>54</sup> Ibid. Art. 6 (3).

<sup>55</sup> European Commission, *Pharmaceutical Sector Inquiry: Final Report* (2009) <<http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/index.html>> 119.

<sup>56</sup> Council Regulation (EC) No. 726/2004 (n 53) Art. 9.

<sup>57</sup> Ibid. Art. 10.

### 2.1.3 Supplementary protection certificate

A supplementary protection certificate (SPC) is the European equivalent of the patent restoration provision of the Hatch Waxman Act in the United States. Just as in the provisions of the Hatch Waxman Act, the SPC Regulation<sup>58</sup> is based on the notion that brand companies may require a patent extension due to the long and costly research involved with innovating new drugs and which, ultimately, results in a reduced term of patent protection. In the absence of such a patent extension, it is argued that the incentives for firms to engage in pharmaceutical research would be diminished, as the return of the companies' investment in R&D could not be guaranteed.<sup>59</sup>

The SPC regulation provides brand companies with the ability to apply for a patent extension for a maximum of five years, which takes effect at the end of the lawful term of the basic patent that the company wants to extend. Under special circumstances this protection can be extended by further six months.<sup>60</sup> The actual additional exclusivity period granted by an SPC is calculated by taking the period between the award of the basic patent and the first valid market authorisation, and reducing it by five years.<sup>61</sup> However, the period of exclusivity shall not exceed 15 years calculated from the date of the first market authorisation in the Union.<sup>62</sup> For this purpose, the applicant has to file an application for an SPC in the Member State in which the product in question is already protected by a basic patent. This application must also include information about the first valid market authorisation for the product and a statement confirming that the product is not already the subject of such a certificate.<sup>63</sup>

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<sup>58</sup> Council Regulation (EC) 469/2009 of the European parliament and the Council concerning the supplementary protection certificate for medicinal products [2009] OJ L 152/1.

<sup>59</sup> Ibid. preamble.

<sup>60</sup> Ibid. Art.13.

<sup>61</sup> Ibid.

<sup>62</sup> Ibid. preamble (9).

<sup>63</sup> Ibid. Art.3.



## 2.2 Marketing authorisation application at the national level

As mentioned above, the centralised procedure is not the only possible means of obtaining market authorisation for a drug in the European Union. This can also be achieved by submitting applications to the relevant national regulatory agencies in the Member States. Two procedures are available for this purpose – the mutual recognition procedure and the decentralised procedure. A common feature of both procedures is that they must be used in cases where the brand company is applying for market authorisation in more than one Member State. Each Member State has to receive an application, including an identical dossier containing the same information that is necessary for the centralised procedure and a list of the Member States to which the applicant has applied.<sup>64</sup>

### 2.2.1 Mutual recognition procedure

The mutual recognition procedure can be utilised if a drug has already been approved in one Member State and the applicant wants to obtain market authorisations for further Member States. In such cases, the Member State that has already approved the market authorisation for the drug will act as a Reference Member State that prepares an assessment report. This report – together with the approved summary of product characteristics, labelling and package leaflet – shall be sent to the Member States concerned and to the applicant that enables the Member State in question to recognise the market authorisation that has already been granted by the Reference Member State.<sup>65</sup> Where a Member State decides that it is not willing to recognise the already approved market authorisation, it needs to provide the other Member States concerned, as well as the applicant, with its reasons for this decision. Based on this submission, these reasons will then be deliberated in a coordination group, consisting of representatives of all Member States concerned.<sup>66</sup> Should this group not be able to come to an agreement, the

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<sup>64</sup> Council Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use [2001] OJ L 311, Art. 28 (1), *'The dossier shall contain the information and documents referred to in Articles 8, 10, 10a, 10b, 10c and 11'*.

<sup>65</sup> Ibid. Art. 28 (2).

<sup>66</sup> Ibid. Art. 29 (1).

application will be referred to the CHMP which will render an opinion on which the European Commission will decide.<sup>67</sup> In case of a dispute between the Member States, the mutual recognition procedure is basically converted into the centralised procedure.

### **2.2.2 Decentralised procedure**

In contrast to the mutual recognition procedure, the decentralised procedure is applicable to cases in which no market authorisation has yet been granted at the time of application. Under this procedure, the same dossier as above is sent to the relevant Member States and the applicant nominates one of these Member States to be the Reference Member State. The designated Reference Member State will then *'prepare a draft assessment report, a draft summary of product characteristics and a draft of the labelling and package leaflet'*.<sup>68</sup> This report is forwarded to all of the Member States concerned. If every Member State approves the assessment, a market authorisation in all these Member States is granted to the applicant. In an instance where a Member State cannot approve the application, the decision is referred to the coordination group of the Member States. From this point on, the procedure takes the same route as for disagreements in the mutual recognition procedure.

### **2.3 Approval of a generic drug following the centralised procedure**

European legislation provides special provisions for the application of generic market authorisation. Just as in the US ANDA, the European Union offers generic companies an abridged application for market authorisation. Following this kind of application, the generic company does not have to provide the *'results of pre-clinical tests and of clinical trials if he can demonstrate that the medicinal product is a generic of a reference medicinal product which is or has been [already] authorised'*.<sup>69</sup> In contrast to the regulatory system established in the United States,

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<sup>67</sup> Ibid. Art. 29 (4), 32, 33, 34.

<sup>68</sup> Ibid. Art. 28 (3).

<sup>69</sup> Ibid. Art. 10 (1).

there is no need for the generic applicant to notify the brand about its abridged application. Furthermore, unlike the US system which intertwines the regulatory procedure of generic drug approval with the granting procedure of patents by the USPTO and the filing of patents in the above discussed Orange Book, the European approach keeps the two regulatory systems separate. European regulations do not provide for a patent linkage. The relevant secondary EU legislation provides that market authorisations shall not be refused, suspended or revoked except on the grounds set out in the Regulation<sup>70</sup> and the Directive.<sup>71</sup> Following these provisions, and the fact no other criteria apart from those regarding public health – such as the safety, the quality and the efficacy of the relevant drug – should be taken into consideration when deciding on the application for a market authorisation, underpin this approach.<sup>72</sup> If it is the case that a market authorisation for a generic version of a drug interferes with the patent status of the brand drug, the issue can be resolved by means of private patent litigation in front of competent courts. The patent protection for a drug is an important issue for the pharmaceutical company, but it is a separate issue altogether with regards to the safety and efficacy of the drug.

However, this is not to imply that patent law issues have no impact on the market authorisation process. In contrast to the US regulatory system, these issues are dealt with by patent law and policy itself and not by the pharmaceutical regulator that might be forced to suspend the application process due to a patent-related dispute. Prior to 31 October 2005, there had not been any legislation on the European level that dealt with the issue of the pre-patent expiry development of generic drugs. The patent laws in most Member States prevented generic companies from engaging in such conduct, as this had been regarded as an infringement of the brand company's patent rights.<sup>73</sup> Yet pre-patent expiry development and testing is necessary for generic companies to be able to apply for market authorisation in time, so they may enter the market as soon as the patent

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<sup>70</sup> Council Regulation (EC) No. 726/2004 (n 53) Art. 81.

<sup>71</sup> Council Directive 2001/83/EC (n 64) Art. 126.

<sup>72</sup> European Commission (n 55) 130.

<sup>73</sup> *Ibid.* 122.

protection of the brand company's brand drug expires. With the introduction of the so-called "Bolar provision" into the European regulatory framework, such development and testing is exempted from patent infringement if it is aimed at the acquisition of a market authorisation by a generic company using the abridged application procedure.<sup>74</sup> This provision provided a lot of legal certainty for generic companies at the European level, as they no longer had to fear patent infringement lawsuits by the brand companies based on this issue. Again, it should be noted that, even though this uncertainty between the different national patent laws existed, it did not directly interfere with the application process for market authorisations, but rather indirectly interfered as the generic companies had to fear patent infringement lawsuits based on the simple fact that they had prepared themselves for market entry.

Although generic companies can develop a generic version of a drug before the patent protection expires, this does not mean that they can start this process on the day the brand drug is sold on the market. To be able to develop such a drug, the generic company requires data from the brand company, such as the results of the pre-clinical tests and the clinical trial which have been produced to show the safety and efficacy of the brand drug. This data is generally protected for a certain amount of time by data exclusivity provisions, which enable the brand company to keep their results secret. Following the amendment of the relevant Directive in 2004,<sup>75</sup> the European legislation now provides brand companies with a mixture of data exclusivity and market exclusivity which is referred to as the "8+2+1 formula". Broken down into words, this formula provides the brand companies with eight years of data exclusivity, two additional years of market exclusivity, and the possibility of extending this market exclusivity by one additional year, if a new therapeutic indication with a significant clinical benefit has been approved within the first eight years of data exclusivity.<sup>76</sup> It is important to understand the distinction between data exclusivity and market exclusivity. Within the first eight

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<sup>74</sup> Council Directive 2001/83/EC (n 64) Art. 10 (6).

<sup>75</sup> Council Directive 2001/83/EC amended by Council Directive 2004/27/EC.

<sup>76</sup> *Ibid.* Art. 10(1).

years of data exclusivity, a generic company that is applying for market authorisation cannot rely on the clinical trial data of the already approved brand drug in an abridged application. After this period has expired, the generic company can apply for market authorisation using the abridged application process. Nonetheless, even if the market authorisation were to be granted within two years, the generic company must refrain from putting its product on the market because of the existing market exclusivity which is between two and three years. However, but the generic company still has the opportunity to *prepare* for market entry, which would not be possible if the brand company simply had ten years of market exclusivity. This would lead to a scenario whereby the generic company would only be allowed to apply for market authorisation using the abridged application procedure after this ten year period had elapsed, which would give the brand company extended market exclusivity due to the time required for the regulatory authority to assess and grant the generic application.

This “8+2+1 formula” replaced the old provisions regarding data protection and came into force on the 30th October 2005. Even though this formula was several years ago, it is still necessary to consider the “old” provisions, as the formula has not been enacted retroactively.<sup>77</sup> Due to this, generic applications which need to take the new data protection provisions into consideration will not occur before 2013.<sup>78</sup> Therefore, every market authorisation application that has been submitted to the EMEA or the national regulatory agencies before 30th October 2005, will still benefit from ten<sup>79</sup> or six<sup>80</sup> years of data protection, depending on the Member State in which this market authorisation was submitted and depending on the regulatory procedure that has to be followed. This period of

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<sup>77</sup> Art 2 and 3 of the Directive 2004/27/EC which amended Directive 2001/83/EC expressly state that the “8+2+1 formula” shall not be applied to cases in which the originator company has submitted an application for market authorisation before 31 October 2005.

<sup>78</sup> European Generic Medicines Association, ‘Data exclusivity’ <http://www.egagenerics.com/gen-dataex.htm> accessed 06 June 2011.

<sup>79</sup> Ten years for national authorisations granted by: Belgium, Germany, France, Italy, the Netherlands, Sweden, the UK and Luxemburg and for authorisations granted on the European level by the EMEA following the centralised procedure.

<sup>80</sup> Six years for national authorisations granted by: Austria, Denmark, Finland, Ireland, Portugal, Spain, Greece, Poland, the Czech Republic, Hungary, Lithuania, Latvia, Slovenia, Slovakia, Malta, Estonia, Cyprus, and also Norway, Liechtenstein and Iceland.

data protection is regarded as the period of ‘data exclusivity’, during which time authorities are prevented from accepting applications. Just as in the United States, this leads to an increased delay of generic market authorisation due to the fact that the application procedure takes between one and three years.<sup>81</sup>

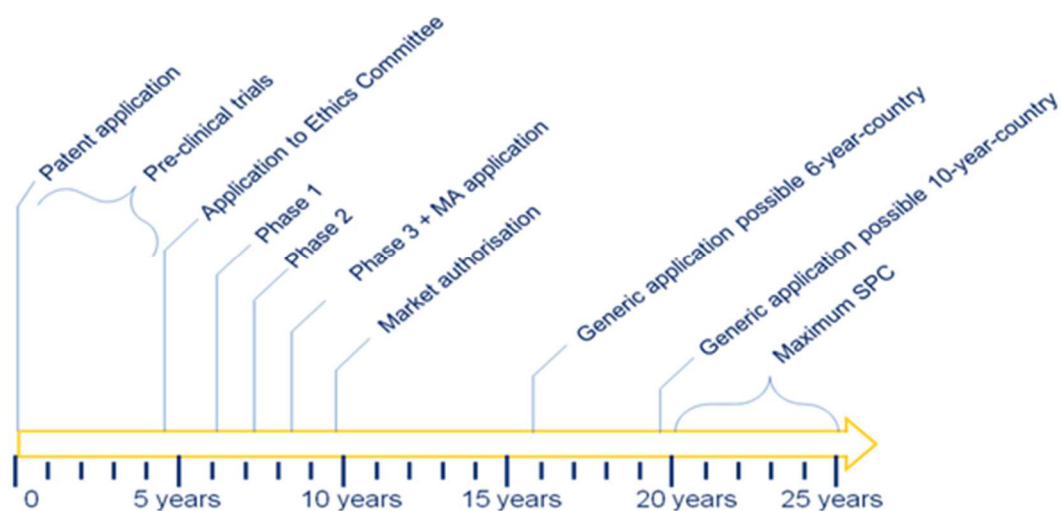


Fig. 12: European drug approval process from 30 October 2005 onwards (8+2+1 formula)

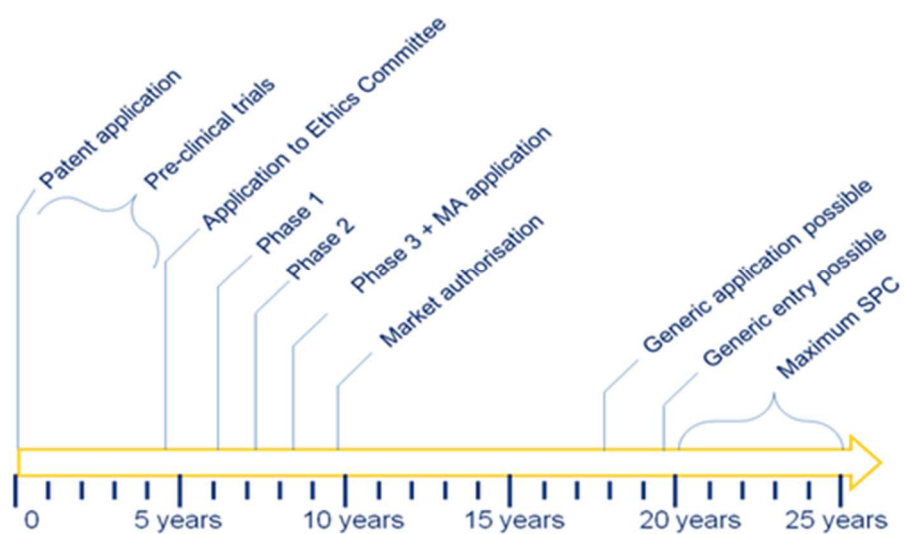


Fig. 13: European drug approval process prior to 30 October 2005

<sup>81</sup> European Generic Medicines Association (n 78).

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