The European approach to the antitrust-patent intersection through the prism of innovation:

in search of more balanced results

Katarzyna Marita Szreder

Thesis submitted for assessment with a view to obtaining
the degree of Doctor of Laws of the European University Institute

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European University Institute
Department of Law

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Ai miei amici -

i miei insegnanti di vita

da cui prendo ispirazione

e su cui posso sempre contare,

- questo lavoro è dedicato.

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This thesis addresses a topical issue of management of the antitrust-patent intersection, looking at the problem from an innovation perspective. It contributes to the field, first, by showing that from the innovation perspective the problem of biases present in both antitrust and patent decision-making might be a matter of concern in managing the antitrust-patent intersection. The question of pro-competition bias is explored through an analysis of novel issues recently considered by antitrust authorities. The analysed case studies concern reverse payment settlements, abuse of the patent system, availability of injunctions in the standard essential patent context and the treatment of the antitrust-patent intersection in the pharmaceutical sector inquiry Report prepared by the Commission. The corresponding risk of a pro-patent bias, already visible in the case studies, is examined in detail through an analysis of the design of the forthcoming Unitary Patent Court.

Second, this thesis offers an examination of a signalling mechanism as a way of addressing the problem of biases. While observing that antitrust cases picked up by the Commission might serve as a signalling device for the patent system intended to prompt an alternative solution to the problem at hand, ways of developing further a communication by signalling outside the realm of enforcement are explored in an attempt to combat the risk of biases and to ensure an effective division of tasks. By adapting a signalling approach this thesis advocates an interdisciplinary approach to antitrust-patent intersection. It also seeks to combine the economic and a regulatory aspect of the treatment of the antitrust-patent intersection, thus giving it an EU-specific angle. The signalling justification for antitrust involvement in patent matters is based on the perception of the inadequacies of the alternative solutions as offered by the patent system, making an antitrust response grounded in the underlying regulatory system.

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LIST OF ABBREVIATIONS

ACM	Authority for Consumers and Markets
AIPLA	American Intellectual Property Association
ANDA	Abbreviated New Drug Application
CAFC	Court of Appeal of the Federal Circuit
CFI	Court of First Instance
CJEU	Court of Justice of the European Union
CMA	Competition and Markets Authority
CTD	Common Technical Document
DG	Directorate General
DoJ	Department of Justice
ECN	European Competition Network
EEA	European Economic Area
EFPIA	European Federation of Pharmaceutical Industries and Associations
EPC	European Patent Convention
EPO	European Patent Office
ETSI	European Telecommunication Standards Institute
FRAND	Fair, Reasonable, and Non-Discriminatory
FTC	Federal Trade Commission
FTCA	Federal Trade Commission Act
IAA	Italian Antitrust Authority
ICT	Information and Communications Technology
IEEE	Institute of Electrical and Electronics Engineers
IP	Intellectual Property
IPEA	Institute for Applied Economic Research
IPLA	Intellectual Property Lawyers' Association
IPR	Intellectual Property Right
NCA	National Competition Authority
OECD	Organisation for Economic Co-operation and Development
R&D	Research and Development
RDP	Regulatory Data Protection
SEP	Standard Essential Patent
SEPA	Single Euro Payment Area
SMEs	Small and Medium Enterprises
SPC	Supplementary Protection Certificate
SSO	Standard Setting Organisation
TFEU	Treaty on the Functioning of the European Union
TRIPS	The Agreement on Trade-Related Aspects of Intellectual Property Rights
TTBER	Technology Transfer Bock Exemption Regulation

UOKiK	The Office of Competition and Consumer Protection
UPC	Unitary Patent Court
UPCA	Unitary Patent Court Agreement
USPTO	US Patent and Trademark Office
WIPO	World Intellectual Property Organisation
WTO	World Trade Organisation

Part I

Chapter 1

Introduction

I. Introduction

1. The application of competition law to matters related to intellectual property rights (IPRs) is an issue that has received considerable attention in the literature. So much so that it can now be considered a separate field of study. Since the early days of the development of the US competition policy, which predates its European counterpart, the question of the appropriate level of competition law involvement in IPR matters raised considerable interest.[1] The answer to that question varied over the years, ranging from a position of complete immunity of IPR to that premised on absolute competition dominance. The enforcement practice on both sides of the Atlantic continues to be in constant search for a workable overarching standard for establishing whether competition involvement is warranted. Numerous academic studies have been devoted to that very question, similarly not reaching a consensus on the point.[2] This should in no way suggest that the issue has become dormant, quite to the contrary, the interface between competition law and IPRs remains perhaps one of the most complex and controversial issues of antitrust policy.

2. Various specific matters at the interface of competition law and IP have been considered by the CJEU over the years. Licensing arrangements, in particular, have been the object of interest of antitrust enforcement. As early as 1962, the Commission issued a Notice on patent licensing agreements, establishing a very light touch approach to IPR matters.[3] While the approach of the Commission to licensing agreements has changed over time, some of the more notable cases concerning

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1 See Herbert Hovenkamp, "IP and Antitrust Policy: A Brief Historical Overview" (December 2005) University of Iowa Legal Studies Research Paper No 05-31; Willard K Tom and Joshua A Newberg, "Antitrust and Intellectual Property: From Separate Spheres to Unified Field" (1997) 66(1) Antitrust Law Journal 167.

2 See e.g. Andreas Heinemann, "The contestability of IP-protected markets", Josef Drexl, "Is there a 'more economic approach' to intellectual property and competition law?", in Josef Drexl (ed), *Research Handbook on Intellectual Property and Competition Law* (EE 2008); Michael Carrier, "Unraveling the Patent-Antitrust Paradox" (2002) 150(3) University of Pennsylvania Law Review 761; Louis Kaplow, "The Patent-Antitrust Intersection: A Reappraisal" (1984) 97 Harvard Law Review 1813; William Baxter, "Legal Restrictions on Exploitation of the Patent Monopoly: An Economic Analysis" (1966) 76 Yale Law Journal 267; Ward Simon Bowman, Jr, *Patent and Antitrust Law: a legal and Economic Appraisal* (University of Chicago Press 1973) Thorsten Käseberg, *Intellectual Property, Antitrust and Cumulative Innovation in the EU and the US* (Hart Publishing 2012).

3 Communication relative aux accords de licence de brevets OJ 1962 P 139/2922, withdrawn in 1984 (OJ C220/14).

licensing arrangements considered by the Court of Justice related to non-challenge clauses contained in a patent licensing agreement (*Windsurfing*),[4] use of trademark licensing to prevent parallel trade (*Consten v Grundig*),[5] exclusive licensing (*Coditel II*,[6] *TetraPak I*,[7] *Premier League/Murphy*[8]*),* culminating with the infamous *Microsoft* case concerning a refusal to license.[9] All of these issues have received considerable attention in the literature.[10] The aim of this thesis is not to repeat the analysis of those problems, but rather to concentrate on the novel questions that troubled the Commission and the Court of Justice more recently (that is reverse payment settlements, abuse of the patent system, and availability of injunctions in the standard essential patent context)[11], as they provide a new insight into the issue of treatment of the IPR-competition intersection. The intention is to see how the Commission and the CJEU build an approach to issues which they did not encounter before. It is in those novel cases that policy reasons for antitrust involvement need to be more openly discussed by the competition authorities to establish a basis for intervention, thus expanding the understanding of the question of the treatment of the antitrust-patent intersection. The added value of relying on those cases lies also in the expectation of a more open policy discussion of the question of the anticompetitiveness of conduct subject to investigation, which is not simply based on fine-tuning the approach established in previous cases. However, to the extent that the treatment of these novel issues builds upon previous cases and the approaches or doctrines adapted therein or contrast with the problems encountered there, previous case law and policy documents remain relevant for this work.

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4 Case C-193/83 *Windsurfing International v Commission* [1986] ECR 00611.

5 Cases 56 and 58/64 *Consten v Grundig* [1966] ECR 299. The issue of limiting of parallel trade through wholesaler agreements was later revisited in Case C-501/06 P *GlaxoSmithKline Services Unlimited v Commission* [2009] ECR I-9291 though not specifically concerning the IPR context.

6 Case 262/81 *Coditel v SA Ciné Vog Films (Coditel II)* [1982] ECR 3381.

7 Case T-51/89 *Tetra Pak Rausing SA v Commission* [1990] ECR II-309.

8 Cases C-4013/08 and C-429/08 *Football Association Premier League Ltd and Others v QC Leisure and Others; Karen Murphy v Media Protection Services Ltd* [2011] ECR I-9083.

9 Case T-201/04 *Microsoft v Commission* [2007] ECR II-3601, see also Case C-238/87 *AB Volvo c. Erik Veng (UK) Ltd* [1998] ECR 6211, Case 53/87 *Renault* [1988] ECR 6039, Joined cases C-241/91 P and C-242/91 P *RTE & ITP v. Commission (Magill)* [1995] ECR I-743; Case C-7/97 *Oscar Bronner* [1998] ECR 7791, Case C-418/01 *IMS Health v Commission* [2004] ECR I-5039.

10 Refusals to licence in particular became a principal point of discussion, see e.g Daniel Beard, "Microsoft: What Sort of Landmark" (2008) 4(1) Competition Policy Int'l 33; Christian Ahlborn and David S Evans "The Microsoft Judgment and its Implications for Competition Policy Towards Dominant Firms in Europe" (2008-9) 75 Antitrust Law Journal 887; Pierre Larouche, "The European Microsoft Case at the Crossroads of Competition Policy and Innovation: Comment on Ahlborn and Evans" (200809) 75 Antitrust Law Journal 933.

11 See further below, para 17ff on selection of the case studies.

3. Whether viewed through a prism of specific problems that come before the competition authorities and courts or as a more general matter, the issue of treatment of the antitrust-IPR interface is connected to an extensive debate concerning the nature of the relationship between competition law and IPRs. Here the approach switched from a perception of the two fields of law as inherently in conflict with each other to one viewing the two fields as complementary.[12] This switch was facilitated by the shift of focus from the methods through which the two fields operate to the common goals these two fields attempt to pursue,[13] the common denominator between competition law and IPRs being the shared goal of incentivising innovation. It would be an oversimplification, however, to say that a shared objective eliminates the tension between the two fields of law, even if at times it might have been exaggerated.[14]

4. However, this change of focus has one important consequence: while many studies in the area discuss the relationship between competition law and all forms of IPR taken together, it might become more appropriate to distinguish between different forms of IPRs. While various forms of IPRs share some common characteristics, they operate differently and the aims and objectives of each kind of right are not perfectly aligned.[15] In particular, the innovation objective is not as apparent when it comes to copyright or trademark protection. Since this study is concerned with building an approach that would incentivise innovative activity, it concentrates on cases related to patents, to the exclusion of cases involving other forms of IPR.[16] While the applicability of the findings to other forms of intellectual property could be an

12 Mark Lemley, "Industry Specific Antitrust Policy for Innovation" (2011) Columbia Business Law Review 637, 638; see further e.g. Luc Peeperkorn, "IP Licences and Competition Rules: Striking the Right Balance" (2003) 26(4) World Competition 527-539, 528 for an example of a complimentarity view.

13 See further ch 2 for a more detailed discussion.

14 Hovenkamp (n 1), p 2.

15 For an overview of aims and objectives of various IPR, see e.g. Michael Spence, *Intellectual Property* (Clarendon Law Series 2007); Robert Mergers, *Justifying intellectual property* (HUP 2011) (for philosophical underpinnings of intellectual property); William Landes, Richard Posner, *The economic structure of intellectual property law* (HUP 2003); Peter S Menell, "Intellectual Property: General Theories", in Boudewijn Bouckaert, and Gerrit De Geest, (eds) *Encyclopedia of Law and Economics, vol 2: Civil law and* Economics (EE 2000) (for a survey of the theoretical intellectual property landscape) or more generally Lionel Bently, Brad Sherman, *Intellectual Property Law* (4th edn, OUP 2014); or Catherine Seville, *EU intellectual property law and policy* (EE 2009).

16 Among some of the more interesting developments that post-date the *Microsoft* case that concern other forms of IPR one could list an investigation of the copyright collecting societies: Case T-442/08 *CISAC v Commission* ECLI:EU:T:2013:188, and 22 other related cases concerning national collecting societies; or Case C-128/11 *UsedSoft GmbH v Oracle International Corp* ECLI:EU:C:2012:407, concerning 'used' software.

interesting question to consider, such consideration must await a separate research project.

5. Another distinguishing feature of this thesis is the fact that it views the relationship between antitrust and patent law as one developing within a particular regulatory setting. It is not just the legal rules that make up that regulatory set up, but also the particular institutional or agency arrangements that may affect the balancing of interests at stake. As things stand now, the EU plays a leading role in building a European antitrust policy, while patents continue to be national rights, with the national courts largely left in charge of interpretation of substantive law.[17] This position is expected to change with the coming into force of the Unitary Patent Agreement and the Agreement on the Unitary Patent Court.[18] This change of institutional scenery makes it a good point to re-evaluate the interaction between the two fields of law, also taking into account the agency set-up and the more practical side of the interaction between the two fields. For this reason, this research project might be considered a European voice among what appears to be a preponderance of US scholarship in this field. It could also be considered timely because of the particular need for a fine-tuned approach to innovation at the antitrust-patent intersection for an ailing European economy recovering from the financial crisis.

6. As innovation constitutes the significant element of this thesis, it naturally relies on the wealth of economic studies concerning that phenomenon, some of which are summarised in chapter 2 to provide a background to the discussion. In fact, economic studies underlining the importance of innovation to economic growth form one of the reasons justifying the undertaking of this project and the shape it takes. The issues considered here are without doubt of huge economic importance, not least because of the amount of money involved in the individual cases subject to inquiry, but even more so because of the effect these decisions might have on future innovative

[17] The patent application process is partially harmonised, with a possibility of applying with a single application through the European Patent Office (EPO) established under the European Patent Convention (EPC) to obtain a bundle of national rights (the European route). In that case, opposition disputes or any other pre-grant disputes can be considered at the European level, by one of the Boards of Appeal alongside the EPO.

[18] The Unitary Patent Protection agreement was established through two Regulations (Regulation (EU) No 1257/2012 of the European Parliament and of the Council of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection; and Council Regulation (EU) No 1260/2012 of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection with regard to the applicable translation arrangements) that came into force on 20 January 2013. However, they will only apply when the Agreement on the Unified Patent Court will come into force and this will occur when 13 Member States ratify it, including three with the greatest number of patent applications (currently France, Germany and the United Kingdom).

endeavours. Both antitrust and patent law can have a significant impact on the innovation process and as such it becomes imperative that they are effective in pursuing their innovation-incentivising role.

7. The economic rationale of the patent system as an innovation-incentivising mechanism itself has been subject to numerous economic studies, with the empirical results failing to provide a conclusive answer to the dilemma.[19] This thesis does not conduct an independent inquiry into that question, but instead relies on previous scholarship on the point and follows the mainstream view according to which the patent system has an innovation-incentivising role to play while recognising that it might be imperfect and suffer from various deficiencies.[20] The deficiencies of the patent system are considered here in so far as improvements to the patent system could provide a response to the problems raised before the antitrust authorities that are subject to this inquiry.

8. At the same time, the role of innovation as one of the goals to be pursued by competition policy among other goals of competition law has also been subject to ongoing legal research and argument.[21] While innovation is not the only goal pursued by competition policy, its position among other objectives pursued by antitrust has to be considered as part of this thesis. It needs to be remembered that treatment of patent issues is just one specific instance in which innovation or efficiency arguments arise as a matter of antitrust law.

II The argument

9. This project starts with an inquiry into select novel EU antitrust enforcement decisions concerning patents to see what might be the problems with antitrust enforcement in this area from the innovation perspective. This analysis and critique is aimed at

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19 Fritz Machlup, "An Economic Review of the Patent System" (1958) Study of the Subcommittee on Patents, Trademarks, and Copyright of the Committee on the Judiciary, Unites States Senate, Study No 15; Landes and Posner (n 16), pp 9-10, fn 32.

20 This is by no means an uncontested view, see e.g. Michele Boldrin, David K Levine, *Against Intellectual Monopoly* (CUP 2008).

21 See Tim Wu, "Taking Innovation Seriously: Antitrust Enforcement if Innovation Mattered Most" (2012) 78 Antitrust Law Journal 313 (putting innovation in the centre of antitrust analysis); Scott Hemphill, "Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem" (2006) New York University Law Review 1553 (advocating focus on allocative efficiencies in practice); Pierre Régibeau and Katharine Rockett, "The relationship between intellectual property law and competition law: an economic approach", ch 10 in Steven D Anderman (ed*), The Interface between Intellectual Property Rights and Competition Policy* (CUP 2007) (separate treatment approach limiting the role of antitrust in analysis of innovation trade-offs).

showing that the Commission and the Court of Justice are faced with a difficult balancing act as a result of a decision that antitrust is an appropriate mechanism to solve the problems at hand. In getting involved in patent matters the competition authorities necessarily become a second filter, a sort of "repair-it-all" mechanism for patent issues, however, not necessarily one that is capable of providing a sufficient balancing of interests at stake or a sufficiently sophisticated remedy.

10. In analysing patent-related cases, the Commission (and also the CJEU), as a specialised competition agency, is at a risk of displaying a pro-competition bias (that is a one sided-view embodied as an inclination for favouring competition understood through short-term goals while undermining or ignoring arguments grounded in incentivising (competition in) innovation) that might be undermining the balance struck as a matter of patent policy, at the expense of innovation. This holds true, even if at times an antitrust intervention might be justified. To an extent, this bias might be a result of a faulty decision-making process concentrated on short-term goals that views grants of exclusivity with hostility,[22] but it might also be a result of inherent limitations of an antitrust agency acting as a specialist body entrusted with promotion of competition and acting within a specific legal framework.

11. At the same time, patent authorities, and the upcoming UPC in particular, might be prone to displaying an opposite pro-patent bias (that is holding a partial perspective expressed as an undue preference for patent expansionism while disregarding the competitive rationale of the patent system). Again, this trend might be inherent to these being specialised bodies, but also a result of a general trend towards patent expansionism (that is left unchecked but for antirust involvement), or insufficient consideration of the competition aspect of the patent system. In consequence, each field of law might be pulling in the opposite direction, rather than striving to achieve a balance between different modes of incentivising innovation which an innovation policy demands.

12. Thus, the main **research question** which this study is trying to answer is how to address the problem of biases which might occur at the antitrust-patent intersection in order to improve the balancing of interests at stake from the innovation perspective given the EU regulatory set-up. Ideally, the two systems should work in a way that

[22] For a view that in the past the Commission has approached patents with hostility, see Valentine Korah, "The Interface between Intellectual Property and Antitrust: the European Experience" (2002) 69(3) Antitrust Law Journal 801-839.

ensures that the incentives to innovate are not undermined. In doing so, due account should be taken of the balancing between the needs of breakthrough innovators and follow-on innovators. It is one of the assumptions of this thesis that this is a task for both antitrust and patent policy to tackle.

13. Although this thesis starts off with the antitrust side of the problem by commencing with an examination of case studies that arose as a matter of antitrust enforcement, in the end it takes a more problem solving, interdisciplinary approach to see how the problems identified through antitrust enforcement could be solved through the patent system. The issues picked up by the EU competition authorities, therefore, serve as a way to open up the discussion beyond the application of a single set of laws to a given problem. While the initial part of the inquiry shows that increased involvement of antitrust authorities in patent related matters is not necessarily matched by more in-depth scrutiny of patent issues or more rigorous balancing of interests at stake, it is argued that the answer to that problem is not separate treatment based on confining each field to its limited role and non-intervention. To the contrary, it is the relative isolationism visible in the EU regulatory set-up that contributes to the problem of potential biases.

14. The thesis, thus, explores how antitrust enforcement can act as a signalling device for the patent system. To that effect, it is argued that more often than not antitrust involvement is really a reaction to a perceived failure of the patent system and a call for the patent authorities to spring into action to resolve the underlying problem that enabled the practice condemned as a matter of antitrust law. If the patent authorities were to react to this signalling in an effective way, it would alleviate the need for antitrust enforcement, which in turn would ease some of the difficulty of dealing with innovation, patent related considerations as matter of antitrust law. While it is not argued that it would eliminate the problem completely, as there might still be instances in which antitrust involvement will be warranted, especially if novel issues arise, an improvement in the antitrust analysis of patent problems would still most certainly be welcome. For such improvement to occur, a mode for the patent system to signal back to the Commission and to the Court that patent policy might be undermined as a result of antitrust involvement needs to be found.

15. It might well be that this signalling cannot be (fully) achieved through enforcement. For this reason, other ways to secure effective interaction between the two fields also need to be looked at. To that effect, some platforms for cooperation already exist,

though not necessarily internal to the EU institutional structure. Yet, it is argued that overall the interaction between antitrust and patent bodies so far remains limited. However, for more balanced results to be achieved, patent law and antitrust need to work in tandem to further an innovation policy.

16. In this way, this thesis joins an economic and regulatory aspect of the treatment of the patent-antitrust intersection, giving it an EU-specific angle. The signalling justification for antitrust involvement in patent matters as explored here is based on the perception of the inadequacies of the alternative solutions as offered by the patent system, making an antitrust response grounded in the underlying regulatory system. Equally the solutions to the problem of biases offered as part of this thesis are tailored to the functioning of the European legal order. The thesis thus strives to add to and combine several strands of literature by considering interaction between antitrust and patent law in a particular regulatory context, rather than simply application of one field of law to issues arising out of the other field.

III Selection of the case studies

17. As already explained above, the case studies selected for in-depth analysis as part of this thesis centre around issues that have been most recently subject to antitrust investigation by the European Commission and the Court of Justice. With the *Microsoft* case reaching different outcomes on the point of anticompetitiveness of a refusal to supply of interoperability information on the two sides of the Atlantic,[23] it became a focal point for discussion of the innovation aspect of antitrust intervention.[24] The European approach as exemplified by the *Microsoft* decision has been strongly criticised by the then Deputy Assistant Attorney General of the Antitrust Division of the US Department of Justice as "harming consumers by chilling innovation and

[23] The doctrine of essential facilities was rejected by the US Supreme Court in *Verizon Communications v Trinko LLP* 540 US 398 124 S.Ct. 872, *inter alia* on the grounds that a competition authority is not a regulatory agency, and thus it "should not impose a duty to deal that it cannot explain or adequately and reasonably supervise" ([7], citing Phillip Areeda, "Essential Facilities: An Epithet in Need of Limiting Principles" (1990) 58(4) Antitrust Law Journal 841, 853) and for fear of false positive results ([7]).

[24] See e.g. Cyril Ritter, "Refusal to Deal and Essential Facilities: Does Intellectual Property Require Special Deference compared to Tangible Property?" (2005) 3 World Competition 281; Damien Geradin, "Limiting the Scope of Article 82 EC: What Can the EU Learn from the Supreme Court's Judgment in Trinko, in the Wake of Microsoft, IMs and Deutsche Telekom?" (2004) 41 CMLRev 1526; Eleanor Fox, "Microsoft (EC) and Duty to Deal: Exceptionality and the Transatlantic Divide" (2008) 4 Competition Policy Int'l 25; Mariateresa Maggiolino, *Intellectual Property and Antitrust: A Comparative Economic Analysis of US and EU law* (EE 2011), ch 5.

discouraging competition."[25] The aim here is to see if the fears already expressed at that point materialised in later cases.

18. Thus, the key to case study selection was (1) issues that arose after the *Microsoft* decision (2) which related to patents (3) that led at least to a Commission decision.[26] The initial choice of case studies was further limited to antitrust cases to the exclusion of merger decisions. While, without doubt, restricting case studies to the area of antitrust constitutes a limitation of this thesis, the scope of research might at the same time be considered expansive, since many of the previously proposed approaches were built with only abuse of dominant position in mind.[27]

19. The exclusion of merger decisions can be justified by the differing nature of the merger inquiry. Firstly, it is performed *ex ante*, while article 101 and 102 cases necessarily involve an *ex post* investigation.[28] More importantly, however, merger decision-making has a more continuous and permanent character, with the type of issues raised being similar in each case. These concern, largely, the relation between mergers (and so market structure) and innovation and the related issue of efficiency defences. Generally, patents feature in merger decisions only to the extent that an acquisition of a more extensive patent portfolio can contribute to the firm's dominant position on the market or can affect its future spending on R&D.[29] There is thus less scope for conflict or direct tension between merger and patent policy that could undermine the latter. Merger policy is not, however, totally excluded from the analysis. It is still referred to, even if not through an in-depth analysis of particular

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25 As cited by Josef Drexl in *Research Handbook on Intellectual Property and Competition Law* (EE 2008), xv.

26 The requirement of a formal decision on the point is dictated by the need of having sufficient materials to analyse. Still, it must be recognised that issues raised by the commentators, such as "patent thickets" (Carl Shapiro, "Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard-Setting" (2000) 1 Innovation Policy and the Economy 119), but not picked by the Commission might be equally telling of the Commission's approach.

27 See, for example Michael Carrier, "Unraveling the Patent-Antitrust Paradox" (2002) 150(3) University of Pennsylvania Law Review 761 (proposing a test for the courts to apply in analyzing monopolists' patent-based actions).

28 See, however, Marie-Anne Frison-Roche, "Le couple ex ante-ex post, justification d'un droit propre et spécifique de la régulation" in Marie-Anne Frison-Roche (eds), *Les engagements dans les systèmes de régulation* (Presses de Sciences Po 2006) for a criticism of this distinction.

29 See M.7559 - *Pfizer/Hospira* and the comments of Commissioner Vestager on the decision: "We have also made sure that the merger of Pfizer / Hospira does not stand in the way of the research and development of medication that could have huge benefits for society" (EC Press Release of 4 August 2015 IP/15/5470); "We only approved the deal after Pfizer agreed to sell the European rights to an arthritis drug it was developing. One concern was that Hospira already had a competing drug on the market, and we thought Pfizer might stop work on its own drug if the deal went ahead as planned. Which would have meant less of the innovation that we depend on as patients" (Speech of 18 April 2016, available at https://ec.europa.eu/commission/2014-2019/vestager/announcements/competition-mother-invention_en (accessed 1 March 2017)).

case studies, in so far as it might be informative in terms of the Commission's approach to innovation or efficiency defences.

20. With these selection parameters in mind, three case studies were initially selected for in-depth scrutiny as part of this project:

> 1) abuse/misuse of the patent system, as explored in the *AstraZeneca* case;[30]
> 2) reverse payment settlements, as examined in *Lundbeck*[31] and *Servier*;[32] and
> 3) availability of injunctive relief for owners of standard essential patents (SEPs), as considered in *Huawei v ZTE*,[33] *Motorola*,[34] and *Samsung*.[35]

21. In addition, a related issue of vexatious patent litigation will constitute a fourth case study as an alternative way of framing of the issues encountered in the other case studies that might tie them all together. Moreover, the first two case studies are closely connected to the Pharmaceutical Sector Inquiry Report prepared by the European Commission pursuant to Article 17 of Regulation 1/2003 EC.[36] Since this document and the monitoring reports that followed it serve as an important source of information on the Commission's approach to the problems encountered in this area, they too are subject to in-depth investigation as part of this thesis and form a fifth case study. While this thesis centres around matters that arise out of case law, documents of this sort are vital material to be considered to have a fuller view of the policy adopted to the problems at stake. Thus, in respect of all case studies, decisions and judgments constitute only a starting point of the inquiry that extends to consideration of various official documents (where they are available).

22. It so happens that the selected case studies come from two contrasting industry sectors: pharmaceuticals (1, 2 and 5) and ICT (3). The contrast between those two industries stems from the different role patents are said to play in them. While reliance

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30 Case C-457/10 P *Astra Zeneca AB and AstraZeneca plc v European Commission*, ECLI:EU:C:2012:770; Case T-321/05 *AstraZeneca v Commission* [2010] ECR II-2805; Case COMP/A. 37.507/F3 *AstraZeneca*, C (2005) 1757 final.

31 Case AT.39226 - *Lundbeck*, C(2013) 3803 final.

32 Case AT.39612 - *Perindopril (Servier)*, C(2014) 4955 final.

33 Case C-170/13 *Huawei Technologies Co. Ltd v ZTE Corp., ZTE Deutschland GmbH*, ECLI:EU:C:2015:477.

34 Case AT.39985 - *Motorola - Enforcement of GPRS Standard Essential Patents*, C(2014)2892 final.

35 Case AT.39939 - *Samsung - enforcement of UMTS Standard essential Patents*, C(2014) 2891 final.

36 European Commission Press Release IP/08/49 of 16 January 2008, "Antitrust: Commission launches sector inquiry into pharmaceuticals with unannounced inspections"; European Commission, Pharmaceutical Sector Inquiry: Final Report of 8 July 2009.

on patents in R&D intensive pharmaceutical sector has been understood to be particularly strong, the importance of the patent system for the information technologies has been questioned. As noted by Bohannan and Hovenkamp, "[i]n some markets, particularly information technologies, innovations become obsolete so quickly that the patent system is little more than a costly nuisance".[37] By contrast, in the pharmaceutical industry the innovation cycle is much longer. Furthermore, network effects play an important role only in the ICT sector.

23. The apparent differences between those two sectors led some commentators to argue that the approach to the antitrust-patent interaction should be industry specific. Carrier, for example, considers these two sectors to be lying at the opposite ends of a spectrum, where at one extreme innovation is patent driven (pharmaceutical industry) and at the other it is competition driven (ICT/ software industries).[38] Not everyone, however, agrees with that division – Tilford, for example, likens pharmaceutical and ICT sectors arguing that both of them have high R&D costs and hence face similar exposure to risk.[39] While it might be considered doubtful whether innovation in the information technology sector is totally indifferent to the influence of patent protection and is only competition driven, undeniable differences in operation between this and the pharmaceutical industry call for an inquiry into the question of how much flexibility is required in dealing with issues at the antitrust-patent intersection to account for those differences. In theory, industry context could change the receptiveness of competition authorities to the patent-based arguments, thus affecting the risk of bias in the decision-making. Increased reliance on patents in the pharmaceutical industry could also be treated as an argument strengthening the need for signalling back. Equally, industry context could affect the Commission's willingness to intervene in patent matters, thus influencing the intensity of communication through signalling. The analysis of the case studies, however, does not suggest that the Commission considered industry context to be relevant in deciding on the intensity or mode of antitrust review. At the same time, significance of these industry sectors, which are both crucial to the EU's economic growth prospects[40] could explain putting those cases

37 Christina Bohannan and Herbert Hovenkamp, *Creation without Restraint: promoting liberty and rivalry in innovation* (OUP 2012).

38 Michael Carrier, "Unraveling the Patent-Antitrust Paradox" (2002) 150(3) University of Pennsylvania Law Review 761.

39 Simon Tilford, "Is EU competition policy an obstacle to innovation and growth?" (2008) Centre for European Reform essays, p 3.

40 ibid, p 4.

among the Commission's priorities. While Europe has never been a market leader in the ICT industry (US companies are leading the way in that sector), its strong position in the pharmaceutical industry has progressively eroded in recent years.[41] Indeed, a decreasing number of innovative drugs reaching the market was one of the chief reasons for the European Commission to initiate a Sector Inquiry into the pharmaceutical sector. While a number of factors might contribute to this situation, it becomes particularly pressing for the competition policy to be in line with the demands of innovation. In spite of the fact that the Commission's recent spur of interest[42] in these sectors might have been induced by the perceived need to protect innovation, the result might be quite to the contrary.[43] Whether this is indeed the case will be the subject of research in Part II.

24. One other common trend that runs through the case studies (possibly with the exception of *AstraZeneca*) is their proximity to the question of use of dispute resolution mechanisms and the corresponding issue of a right of access to justice. Without doubt, this could constitute a further complication for the analysis to be performed, since it introduces an additional variable to be considered when analysing those cases. Considerations such as right of access to justice cannot be completely ignored despite them being separate from the aims and objectives of the antitrust and patent systems, since they affect the final outcomes of cases. This proposition must stand even if innovation was to be treated as the sole objective to be pursued as a matter of antitrust and patent policies. At the same time, access to justice can be considered not solely as a fundamental right, but also as part of the subject-matter of the patent. It is thus possible to integrate it into the analysis that is innovation centred and to internalise the issue as one concerning the balancing of the interaction between antitrust and patent law, thus avoiding external considerations.

41 ibid.

42 At the time of writing pharmaceuticals and ICT are no longer listed among Commission enforcement priorities: speech by Margethe Vestager, "Setting priorities in antitrust" of 1 February 2016, GCLC, Brussels, available at http://ec.europa.eu/commission/2014-2019/vestager/announcements/setting-priorities-antitrust_en (accessed 6 February 2016).

43 It has been claimed that innovator firms have become an object of antitrust enforcement, raising doubts as to whether this can be justified from the innovation perspective: see Keith N Hylton, "A Unified Framework for Competition Policy and Innovation Policy" (2013) Boston University School of Law Working Paper No 13-55, p 1.

IV Structure of the paper

25. This thesis is composed of three Parts. The first Part sets down the parameters of research – its scope, purpose, contribution to the field – and defines the research question together with a short explanation of the argument pursued (chapter 1). It also lays down the foundational assumptions that inform the approach to the analysis in Part II (chapter 2).

26. Part II contains an examination of the case studies. The purpose of this Part is twofold: first, it is to observe and analyse the regulatory choices made, i.e. whether antitrust intervention was justified and on what grounds. Second, examination of the antitrust analysis performed pursuant to those regulatory choices is aimed at revealing any problems that might arise out of the approach taken to the treatment of the antitrust-patent intersection in those cases. The focus is in particular on showing that antitrust intervention might be at risk of displaying a pro-competition bias. While acknowledging that not every rebalancing of the patent system might have negative consequences for the innovative process, the existence of a pro-competition bias is seen as having a potential to undermine incentives to innovate in the patent context as a result of an insufficient consideration of the competing interests at stake. Any negative effects that antitrust involvement might have for the functioning of the patent system (and the system of incentives it establishes) are also at the centre of the attention of the analysis. While the selected case studies concern the EU approach to the issues that are subject of this research, Part II also takes an opportunity to compare the European approach with that applied in the US in respect of similar questions. This comparison will allow for a better understanding of the peculiarities of the EU approach by putting it in perspective as well as for eventual criticism resulting from discovery of omissions or deficiencies that are thus revealed. In line with the approach set out above, the aim is not simply to criticise outcomes of individual cases, but rather to focus on the reasoning process that leads to those outcomes.

27. The analysis performed in Part II provides a basis for answering the research question, a task which is attempted in Part III. That Part contains a more general discussion of the policy questions at play. Before considering the ways in which the problems revealed in Part II could be solved, it discusses the relevant features of the underlying institutional and agency framework (chapter 9). In connection to that, the design of the forthcoming Unitary Patent Court is discussed to reveal the potential of a pro-patent

bias operating in the opposite direction to the pro-competition bias, a phenomenon which might be already visible in Part II. The final chapter builds on the findings of the earlier chapters to discuss ways in which both types of biases in the decision making at the antitrust-patent intersection can be countered to achieve more balanced results (chapter 10). It is in this chapter that the signalling mechanism and an interdisciplinary problem-solving approach to the antitrust-patent interaction is discussed in detail.

Chapter 2

Innovation and the patent-antitrust intersection – foundational assumptions

I Introduction

1. In recognition of the importance of innovation to economic growth, Innovation Union constitutes one of seven flagship initiatives in Europe 2020 growth strategy[1] aimed at creating "a vibrant, innovation-based economy fuelled by ideas and creativity".[2] The strategy envisages that all EU policies, instruments and legal acts "should be mobilised to pursue the strategy's objectives".[3] While positive action to stimulate investment in research comprises a great part of the strategy,[4] EU competition policy forms a vital element in creating an innovation-friendly environment and as such it should be in line with the European growth strategy. Equally, on the intellectual property side the Commission seeks to promote efficient and effective enforcement of intellectual property to ensure stimulation of investment.[5]
2. This chapter discusses the role of each antitrust law and the patent system in promoting innovation and the treatment of the innovation dimension at the patent-antitrust intersection. It also expounds on the understanding of innovation in this context and its role in creating economic growth. This is done with a view to establishing a framework for discussion in the other parts of this thesis. This chapter thus merely aims at establishing "the basic elements of the puzzle", rather than having a fully fledged discussion of the arguments, which in themselves could form a basis of a separate thesis.
3. As it will be seen in the discussion that follows, neither the promotion of competition nor the promotion of innovation are seen here as falling within the exclusive domain of

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1 European Commission, Communication from the Commission of 3 March 2010, Europe 2020: A strategy for smart, sustainable and inclusive growth, COM(2010) 2020 final.

2 European Commission, State of the Innovation Union 2012 Accelerating change, Communication from the Commission to the European Parliament, The Council, the European Economic and Social Committee and the Committee of the Regions of 21 March 2013, COM(2013) 149 final.

3 ibid, p 20.

4 See Horizon 2020, a multibillion research programme implementing Innovation Union Strategy: https://ec.europa.eu/programmes/horizon2020/ (accessed 1 March 2017), which is the world's biggest research programme according to the European Commission, "White Paper on the Future of Europe, Reflections and Scenarios for the EU27 by 2025" COM(2017)2025 of 1 March 2017, p 8.

5 See European Commission, "Public consultation on the evaluation and modernisation of the legal framework for the enforcement of intellectual property rights" of 14 Sept 2016.

either set of laws (antitrust or the patent system). Instead, the issue is considered to be multidimensional. This multidimensional understanding of the roles of each set of laws is compounded with a grounding assumption that both the state of competition and patent exclusivity have a role to play in incentivising innovation.

4. Thus, it is understood that a competition authority's task of creating an innovation-friendly regulatory framework is not limited to assessing the impact of its decisions on the parties' long term incentives in the case at hand, but also extends to creating a conscious policy to manage the division of functions between itself and the patent authorities, bearing in mind that its regulatory choices might have an impact on other fields of law. Moreover, this line of reasoning presupposes that there is a link between regulatory choices in this sphere and the demands on the deliberation process in individual cases that has a direct effect on the innovation dimension. In other words, a pro-innovation policy demands that a more interventionist regulatory choice on the part of the competition authorities in respect of cases touching upon the patent system requires an adaptation of the decision-making process, so as to increase its sensitivity and engagement in the balancing of different interests at stake.

5. This chapter is divided into three sections for ease of analysis: the section that immediately follows this introduction concentrates on the role of innovation in antitrust analysis. It is in this part that the understanding of innovation that will be used throughout this thesis is introduced. The next section, in turn, discusses the role of patent exclusivity in promoting innovation**.** The last section discusses innovation specifically at the patent-antitrust intersection. It reveals the multidimensional approach to the patent-antitrust intersection that informs this study and discusses the regulatory dimension of the issue bearing in mind the innovation perspective that is applied to the problem.

II Innovation policy as realised by competition bodies

The concept of innovation in the antitrust context

6. The concept of innovation can be considered rather indeterminate especially since there exists no universally agreed definition of innovation. While it covers an enormous variety of situations, it could be simply defined as an activity that creates economic growth, but that circular definition does not add much to the debate.

Following Rogers[6] we can describe it as a three stage process, where the first phase is the invention of a new element (or a new combination of old elements), followed by commercialisation stage and an imitation stage (diffusion). While Rogers was principally interested in the third stage, in the current context the object of interest lies with creating a regulatory environment that incentivises practically useful inventions (i.e. stage one proceeding to stage two).[7] Naturally, the third stage of the innovation cycle also remains relevant in so far as it creates pressure that incentivises further innovative activity. The role of generic producers in putting such pressure on the originators (i.e the innovators) will be particularly relevant when discussing the pharmaceutical cases in Part II of this thesis. Apart from distinguishing different stages in the innovation process, one can also distinguish different forms of innovative activity. Schumpeter offers a rather wide-encompassing definition of innovation distinguishing between five types of categories of events: product innovation, process innovation, organizational innovation, market innovation, and input innovation.[8] In the antitrust-patent context only the first two forms of innovative activity are immediately relevant. Innovation can also be categorised on the basis of the type of contribution it makes to the field. The basic distinction that is often used is between breakthrough and incremental (also known as follow-on) innovation, but it is also possible to distinguish between radical, recombination or improvement innovations among others.[9] Although varying in the level of novelty required, all of these types of innovation require a "qualitative leap" that turns those events into something more than an ordinary process of change.[10] All of these types of innovation are potentially relevant in the present context and, as it will be seen in Part II, the analysis of what innovation requires might necessitate distinguishing between those different forms of innovation as they might be pointing in different directions. To give an example, the innovative interests of

6 Everett M Rogers, *Diffusion of innovations* (4th edn, 1995).

7 In contrast, Schumpeter concentrated on stage two and the work that needs to be done by entrepreneurs to market inventions.

8 As per Jon Sundbo, *The Theory of Innovation: Entrepreneurs, Technology and Strategy* (Edward Elgar 1998), p 20; and Jati Sengupta, *Theory of Innovation: A New Paradigm of Growth* (Springer 2014), p 4.

9 See ibid, pp 21 and 31 respectively. Radical innovation brings about something very new that replaces the old solution and changes the whole field (it can also be referred to as disruptive innovation, see for example Alexandre de Steel and Pierre Larouche, "Disruptive Innovation and Competition Policy enforcement" (2015) Background Note, OECD Global Forum on Competition, DAF/COMP/GF(2015)7); breakthrough innovation brings about a new product or process without necessarily replacing the old one; recombination innovation uses previously known elements together in a new way; improvement innovation improves quality of a known invention, and incremental innovation builds upon previous invention.

10 Sundbo (n 8), p 21.

breakthrough innovators might point in the direction of stronger IP protection, while those of the follow-on innovators might call for less expansive understanding of patent rights. This can be translated into the antitrust context, where the relative positions of breakthrough and follow-on innovators might also be in the balance, for example when it comes to the availability of injunctions in the standard essential patent context, as discussed in chapter 6.

7. Finally, it has to be clarified that innovation does not denote exactly the same meaning as dynamic efficiency, although the terms are sometimes used interchangeably. Rather it might be more fair to say that "innovation generates welfare gains due to dynamic efficiencies."[11] A situation can be described as dynamically efficient if an optimum level of innovative activity is achieved.[12]

Innovation as one of the objectives of antitrust law

8. Although the objectives of antitrust are not clearly spelt out in the Treaties,[13] as things stand now the promotion of innovation as such is generally not considered the paramount objective of competition law, despite the fact that arguably it should be. Yet, it might be seen as being comprised within the consumer welfare standard which appears to be taking the lead as an objective of competition law in Europe.[14] Its position within that standard, however, is not entirely clear, despite considerable debate on the question of the role that innovation should play in competition law enforcement.[15] In so far as the consumer welfare standard is about securing efficiency,

11 Doris Hildebrand, "The European School of EC Competition Law" (2002) 25 World Competition 3, p 8.

12 "Dynamic efficiency implies that the flow of surplus realized through the introduction of new products or processes over time, net of the cost of researching and developing these new products and processes, is at the maximum": Andrew Tepperman and Margaret Sanderson, "Innovation and dynamic Efficiencies in Merger Review, Final Report" (2007) CRA Project No. D09208-00, prepared for the Canadian Competition Bureau, p 5.

13 Cf Wouter PJ Wils, "The Judgment of the EU General Court in *Intel* and the So-Called More Economic Approach to Abuse of Dominance" (2014) 37(4) World Competition 405, pp 417-418 who claims that the Treaties clearly specify the objective of antitrust law to be the protection of the competitive process as such, relying *inter alia* on the wording of Protocol 27 annexed to the Treaty of Lisbon ('system of undistorted competition'); however, even if the goal of antitrust is considered to be protection of competition, that presumably also includes competition for innovation.

14 As opposed to the total welfare standard; Joaquin Almunia SPEECH/1/2003803 "Competition - what's in it for consumers?", 24 November 2011: "Consumer welfare is not just a catchy phrase. It is the cornerstone, the guiding principle of EU competition policy"; Guidelines on the application of Article 101 of the Treaty on the Functioning of the European Union to technology transfer agreements, OJ C89/2014 of 29 March 2014: "The aim of Article 101 of the Treaty as a whole is to protect competition on the market with a view to promoting consumer welfare and an efficient allocation of resources."

15 See, for example Jonathan B Baker, "Beyond Schumpeter vs Arrow: How Antitrust fosters innovation" (2007) 74 Antitrust Law Journal 1; Keith N Hylton, "A Unified Framework for Competition Policy and Innovation Policy" (2013) Boston University School of Law Working Paper No 13-55.

dynamic efficiency is balanced against allocative and productive efficiencies, which might often pull in a different direction.[16]

9. Despite there being a broad consensus among academics that the gains to be had from dynamic efficiency far outweigh the gains to be had from static efficiency[17] and numerous assurances at the official Commission level about the importance of innovation,[18] it appears that in practice the Commission and the Court of Justice (CJEU) often concentrate on short-term static efficiency at the expense of dynamic efficiency. This trend will be visible also in the case studies considered in Part II.

10. It also remains debatable to what extent the goal of dynamic efficiency, or innovation more broadly, needs to 'compete' with other non-economic goals that antitrust policy might pursue such as protection of fair competition, individual economic freedom,[19] or other socio-political objectives such as protection of the environment or employment. In the EU context the creation and support of the internal market might also be seen as one of the objectives of antitrust.[20] This last objective might indeed be seen as one of the distinguishing features of the EU competition system that differentiates it from any other antitrust regime.

11. Either way, when faced with an immediate and more definite short-term loss that the consumer might incur, dynamic efficiency is often on the losing side of the equation. This short-sighted view of the consumer welfare approach, however, might lead to suboptimal results, since, as pointed by Bishop and Walker, firms might lose incentives to invest in research and development to the detriment of consumers.[21] Clearly, there is space for the innovation dimension within the consumer welfare standard (indeed an important one), albeit unfortunately in practice it is not always realised.

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16 See for example Roger J Van den Bergh and Peter D Camesasca, *European Competition Law and Economics: A Comparative Perspective* (2nd edn, Sweet & Maxwell 2006), p 29; Andrew Tepperman and Margaret Sanderson, "Innovation and dynamic Efficiencies in Merger Review, Final Report" (2007) CRA Project No. D09208-00, prepared for the Canadian Competition Bureau, pp 6-7.

17 Herbert Hovenkamp, "Antitrust and Innovation: Where We are and Where We should be" (2011) 77(3) Antitrust Law Journal 749, p 751, see also discussion below at para 13.

18 See for example Joaquín Almunia's speech: "Competition, innovation and growth: an EU perspective on the challenges ahead", of 21 November 2013 at Third BRICS International Competition Conference, SPEECH/13/958.

19 See for example Amartya Sen, "Markets and Freedoms: Achievements and Limitations of the Market Mechanism in Promoting Individual Freedoms" (1993) 45(4) Oxford Econ Papers 519.

20 Alison Jones and Brenda Sufrin, *EU Competition Law* (4th edn, OUP 2011), 42: "EU competition law can be seen as serving two masters, the 'competition' one and (even more demanding) the imperative of single market integration."

21 Simon Bishop and Mike Walker, *The Economics of EC Competition Law* (3rd edn, Sweet & Maxwell 2010), para 2-019.

12. The reasons for the incentivising of innovation being a goal worth pursuing are rather straightforward: innovation is largely undisputedly considered to be the key to economic growth. Empirical evidence shows a positive link between innovation and economic performance.[22] Indeed, it has been described as "the single most important factor in the growth of real output."[23] Virtually all of the available scholarship points to the fact that fostering innovation is more important than achieving static efficiency.[24] As early as in 1957 Solow estimated that 87.5 per cent of gross output is attributable to technical change.[25] While later re-appraisals led to a reduction of "Solow's residual",[26] the basic premise that innovation is responsible for a large part of gross output remains unquestioned by empirical research. This led Hylton to conclude that innovation at a monopoly cost is better than no innovation at all.[27] Given the importance of innovation, it might be considered disappointing that relatively little work is done to incorporate innovation concerns into antitrust enforcement.[28]

Problems with incorporating the innovation dimension in competition analysis

13. Despite the fact that there remains little controversy over the benefits resulting from innovation to economic growth and thus to consumer welfare, more questions arise in respect of antitrust's ability to engage in the analysis of the dynamic situation that it entails. The problem has both a theoretical and a practical dimension.

14. On the theoretical side, the relationship between the state of competition and innovation has not as yet been established beyond doubt. Two major contrasting positions on the dynamics of innovation can be distinguished. According to

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22 A number of indices have been developed to measure innovative capacity of countries, e.g. Innovation Capacity Index (ICI), Global Innovation Index, Innovation Union Scoreboard (EU centred). Countries scoring high in those indices are usually top economic performers.

23 Joseph F Brodley, "The Economic Goals of Antitrust: Efficiency, Consumer Welfare, and Technological Progress" (1987) 62 NYU Law Review 1020, p 1026.

24 Robert M Solow, "Technical Change and the Aggregate Production Function' (1957) 39(3) The Review of Economics and Statistics 312-320; Gavin Cameron, 'Innovation and Growth: a Survey of Empirical Evidence" (1998) available at http://www.nuff.ox.ac.uk/users/cameron/papers/empiric.pdf (accessed on 22 January 2016); Elhanan Helpman, *The Mystery of Economic Growth* (The Belknap Press of Harvard University Press 2004), pp 34-55; see also Tim Wu, "Taking Innovation Seriously: Antitrust Enforcement if Innovation Mattered Most" (2012) 78 Antitrust Law Journal 313, 313; Herbert Hovenkamp, "Competition and Innovation" in David Crane and Herbert Hovenkamp (eds), *The Making of Competition Policy: Legal and Economic Sources* (OUP 2013), p 282.

25 Solow (n 24).

26 Gene M Grosman, Elhanan Helpman, *Innovation and Growth in the Global Economy* (The MIT Press 1991), p 6.

27 Hylton (n 15), p 11.

28 ibid, p 3.

Schumpeter monopoly environment is conducive to innovation.[29] His theory is based on an idea that only firms that are free from competitive pressure have sufficient resources available to devote to research. To the contrary, Arrow doubted the incumbent's willingness to innovate when freed from competitive pressure.[30] According to him it is the conditions of competition that foster innovation. He has argued that by innovating the incumbent firm is losing its profits from the existing invention, so its incremental incentive to innovate is lower than that of the new entrant – a phenomenon described as the replacement effect by Tirole.[31] Arrow's analysis is influential, but not sufficiently general to conclude that competition is conducive to R&D.[32] Moreover, the replacement effect can be countered by the incentive to preempt competition on the part of the monopolist.[33] Whichever theory is applied, however, there is a role to play for antitrust in promoting innovation, for even on the Schumpeterian view, the process of creative destruction created by breakthrough innovators fighting for a monopoly position is a form of competition for the market that should be protected.[34] Under Schumpeterian approach competition law involvement does not become unnecessary, it is only that its focus should not be to indiscriminately ban "all restrictive behaviour without taking into account the virtues of creative destruction."[35]

29 Joseph A Schumpeter, *Captitalism, Socialism and Democracy* (Harper & Row 1962).

30 Kenneth J Arrow, "Economic Welfare and the Allocation of Resources for Invention", in R Nelson (ed), *The Rate and Direction of Inventive Activity: Economic and Social Factors* (Princeton University Press 1962).

31 Jean Tirole, *The Theory of Industrial Organization* (MIT Press 1988).

32 Richard J Gilbert, "Competition and Innovation", in Wayne Dale Collins (ed), *ABA Section of Antitrust Law: Issues in Competition Law and Policy*, vol 1 (ABA Publishing 2008); in particular his results do not apply directly to product innovation: Richard Gilbert, "Looking for Mr. Schumpeter: Where are We in the Competition-Innovation Debate?" (2006) 6 Innovation Policy and the Economy 159, p 167.

33 The strength of the incentive to preempt will depend on the ability of the incumbent to forestall competitors through its innovative activity and the R&D situation of the competitors, see empirical studies on the topic by Richard Gilbert, David Newbery, "Preemptive Patenting and the Persistence of Monopoly" (1982) 72 American Economic Review 514; Jennifer F Reinganum, "Uncertain Innovation and the Persistence of Monopoly" (1983) 73 American Law Review 741.

34 Alexandre de Steel and Pierre Larouche, "Disruptive Innovation and Competition Policy enforcement" (2015) Background Note, OECD Global Forum on Competition, DAF/COMP/GF(2015)7, para 15, citing H.A. Shelanski "Information, Innovation, and Competition Policy for the Internet" (2013) 161 University of Pennsylvania Law Rev 1663-1705, p 1693; but see further Joseph Gregory Sidak, "Debunking Predatory Innovation" (1983) 83(5) Columbia Law Review 1121 for a discussion and criticism of the Ordover and Willig model of predatory innovation whereby even genuine innovations can sometimes be seen as anticompetitive when an innovation brings about a redesign causing incompatibility with other products.

35 Josef Drexl, "Is there a more 'economic approach' to intellectual property and competition law?", in Josef Drexl (ed), *Research Handbook on Intellectual Property and Competition Law* (Edward Elgar 2008), p 41.

15. While empirical research on the point remains inconclusive,[36] an influential recent study by Aghion et al suggests a middle ground: an inverted U relationship between the level of competition and innovation.[37] This model considers the innovative activity of both the leaders and the followers (laggards) in different competitive conditions. It holds that the incentives to innovate depend upon the difference between post-innovation and pre-innovation rents of incumbent firms, rather than simply on post-innovation rents. In this system two possible effects can occur: in a neck-and-neck industry competition can reduce pre-innovation rents leading to an "escape the competition" effect (increasing innovation among leaders), whereas the Schumpeterian effect should dominate in respect of laggard firms where neck-and-neck is not the case (meaning that competition can also reduce incentives to innovate among the laggards). The model devised by Aghion et al suggests that in these conditions peak innovative activity occurs in the medium conditions of competition.

16. Equally on the practical side, embracing the innovation dimension by competition authorities runs into problems that are also associated with uncertainty. Adding a temporal element into the analysis necessarily complicates it, since it is argued that it requires making predictions into the future. Yet, while innovation necessarily occurs within the conditions of uncertainty – different schools of thought emphasise that element to a varying extent[38] – it is not necessary for competition law to second guess the winner of the innovation game. Indeed, to do so would go against an understanding of the dynamics of the innovation process as a trial an error process in the conditions of

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36 For an overview of empirical studies looking for links between R&D and market structure see Richard Gilbert (n 32).

37 Philippe Aghion, Nicholas Bloom, Richard Blundell, Rachel Griffith, and Peter Howitt, "Competition and Innovation: An Inverted U Relationship" (2002) NBER Working Paper Series 9269; the findings have been criticised by some commentators, see for example: Goeffrey A Manne and Joshua D Wright (eds), *Competition Policy and Patent Law under Uncertainty: Regulating Innovation* (Cambridge University Press 2011), p 10; they can be criticised *inter alia* for the method of measuring innovation, which is by the average number of patents taken out by firms in the industry weighted by the number of times each patent has been cited. It could be argued, however, that patent use is not a reliable proxy for the level of innovation in the industry.

38 Evolutionary theory, as represented by Nelson and Winter, emphasises the element of uncertainty in the process of innovation and is based on bounded rationality whereby heterogeneous firms have information limitations. Similarly, the Austrian school concentrates on uncertainty and postulates a concept of "sheer ignorance" as characterising the process of innovation, whereby knowledge is never complete and always subjective. In this model advertising and market exchange are firms' responses to uncertainty. Path dependence, on the other hand, sees the process of innovation as exploration of different possibilities. It warns against possible lock-ins resulting from irreversible investments that might lead to inefficient results and long-standing dominance; for an overview of different dynamic competition theories see Jerry Ellig, Daniel Lin, "A Taxonomy of Dynamic Competition Theories", in Jerry Ellig (ed), *Dynamic Competition and Public Policy: technology, innovation, and antitrust issues* (CUP 2001).

uncertainty.[39] The aim of antitrust law should rather be to protect the dynamics of the innovation process itself. This is an approach which has been already suggested by Drexl, who proposes to replace the dynamic efficiency standard, which is effects-based and relates to the use of resources for the development of the yet unknown products (that may or may not materialise in the future), with a process-based concept of dynamic competition.[40] Under this approach the process-oriented concept of dynamic competition is used to protect competitive process that enhances innovation.[41] The emphasis is thus put on incentivising innovative activity rather than on welfare gains or losses of an intervention, which might be impossible to predict. This approach is not only more achievable in the practical sense due to the fact that it avoids prospective welfare assessments and changes the focus of the inquiry to the present circumstances in the market and the incentives of the market players to innovate, but also it is simply more logical as a matter of innovation policy (failure being part and parcel of the innovation process).

17. Consequently, the practical problems with the incorporation of the innovation dimension in antitrust analysis might not be as great as they at first appear, if one concentrates on the process of innovation itself. The problem then becomes more of a question of abandoning old habits of grounding the analysis in neoclassical economics acquired by the competition authorities.[42] The real difficulty lies rather with making a trade-off assessment between different objectives. When it comes to the theoretical problems, on the other hand, all major schools of thought see a positive link between innovation and competition. The economic literature in this context is quite rich and it is rather a question of battling "a wrong perception that scholars have not yet filled an intellectual void."[43] If anything, it is competition agencies that are lagging behind in this respect. Even if contemporary scholarship has not yet found a way for identifying an optimum solution, a suboptimal solution that engages in the dynamic analysis might be better than a rejection of the dynamic framework through prevalence of static analysis, given the importance of innovation to economic growth – that much is clear

39 ibid.

40 Drexl (n 35), pp 39-40.

41 ibid, p 40.

42 David J Teece, "Favoring Dynamic over Static Competition: Implications for Antitrust Analysis and Policy", in Manne and Joshua D Wright eds, *Competition Policy and Patent Law under Uncertainty: Regulating Innovation* (CUP 2011), 205: "... the enforcement agencies are not confident about discarding 'conventional wisdom', despite the fact that many of them are aware that much of it is deeply discredited."

43 ibid, p 205.

from the wealth of scholarship. In connection to that, it might be also worth recognising that false positive results stemming from undue focus on short-term effects might be more damaging than the cost of failing to censure anti-competitive practices, as suggested by the work of Evans and Padilla.[44]

III The role of patent exclusivity in promoting innovation

18. Previous section discussed the general issues pertaining to the relationship between competition and innovation. Before turning to the question of the nature of the interaction between antitrust and the patent system, this section discusses first the rationale behind the patent system. This will facilitate the discussion of the interaction between patent and antitrust law. In comparison to competition law, the innovation-incentivising role of patent law has been traditionally more pronounced. While just like any other property right it could be described as aiming at securing control of assets, thus being a mechanism for maintaining peace and order,[45] the whole patent system is built around the need to incentivise innovation. Currently, this economic approach to patents seems to be largely replacing justifications grounded in natural rights or justice.[46]

19. Importantly, patents are granted only in respect of specified types of revealed inventions, that is practical applications of scientific knowledge and not merely abstract ideas. It is not simply about recouping investment, since only successful investments are rewarded.[47] The grant of exclusivity is working as a rewarding mechanism through which investment in innovation is incentivised.[48] At the same time, the diffusion of information about the invention enabled by the patent system helps follow-on innovation, since other inventors can build on the available knowledge. The policy on

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44 See David S Evans and Jorge Padilla, "Designing antitrust rules for Assessing Unilateral Practices: A Neo-Chicago approach" (2005) University of Chicago Law Review 73.

45 Pierre Régibeau, Katharine Rockett, "The relationship between intellectual property law and competition law: an economic approach", in Steven D Anderman (ed), *The Interface between Intellectual Property Rights and Competition Policy* (CUP 2007), p 508.

46 Fritz Machlup, Edith Penrose, "The Patent Controversy in the Nineteenth Century" (1950) 10(1) The Journal of Economic History 1, p 11 ff; Machlup identifies four theories through which patent law could be justified: incentive theory, reward theory, disclosure theory and natural law theory (Fritz Machlup "An Economic Review of the Patent System" (1958) Study of the Subcommittee on Patents, Trademarks, and Copyright of the Committee on the judiciary, Unites States Senate, Study No 15).

47 Drexl (n 35), p 50.

48 The rewarding and the incentivising function of patent law might be viewed as two sides of the same coin, similarly there is an overlap between a reward and a natural law theory of patents: David T Keeling, *Intellectual Property Rights in EU Law: Free Movement and Competition Law* (OUP 2003), p 244.

the scope of patent protection is crucial for future innovation – too narrow patent protection will not provide sufficient incentives to innovate to would-be patentees, while too broad scope of protection might discourage patentee's competitors from joining or continuing "the invention game".[49]

20. While a grant of a patent equals to a grant of exclusivity over an invention, in the present context it is important to underline that the patent system in many instances also creates competition that would not have existed otherwise. On the one hand, investors are inclined to invest in areas which free-riding would otherwise make unprofitable thus creating markets, and on the other hand other producers try to invent around the protected invention, since patent protection extends only to specific applications revealed in the patent application. In this way the patent system creates competition for the markets as well as within the markets. Also, the fact that a product is covered by patent protection often features as a selling point in merchandising strategies,[50] which shows how innovativeness can be a parameter of competition.

21. While the majority of studies agree with this characterisation of the way patents work, this view is not universally held – Baldwin and Levine are among scholars who deny patent utility and consider it damaging since it gives the patentee not only rights over the invention, but also control over price.[51] The ability to control prices, however, comes only with market power and it is widely accepted that a grant of exclusive rights over an invention does not in itself amount to securing market power.[52] Still, as noted by Landes and Posner, the literature on the economic effects of patents is inconclusive and that the "belief [that without legal protection the incentives to create intellectual property would be inadequate] cannot be defended confidently on the basis of current knowledge"[53] Similarly, an earlier Machlup's review of patents concluded that "[n]o economist, on the basis of present knowledge, could possibly state with certainty that the patent system, as it now operates, confers a net benefit or a net loss upon

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49 R Merges, R Nelson, "On the Complex Economics of Patent Scope" (1990) 90 Columbia Law Review 839, p 916.

50 Lionel Bently, Brad Sherman, *Intellectual Property Law* (2 edn, OUP 2004), p 328.

51 Michele Boldrin, David K Levine, *Against Intellectual Monopoly* (CUP 2008).

52 See, Case C-457/10 P *Astra Zeneca AB and AstraZeneca plc v European Commission*, not yet reported, on the question of dominance confirming previous line of case law (Joined Cases C-241/91 P and 242/91 P *RTE and ITP v Commission (Magill)* [1995] ECR I-743; Case C-418/01 *IMS Health* [2004] ECR I-5039). Boldrin and Levine's assertion concords with misleading statements that patents equate to a monopoly. Even successful inventions might face competitive pressure in the market they operate in or from the competitors fighting for the market (drastic innovation replacing the demand for a product).

53 William Landes and Richard Posner, *The Economic Structure of Intellectual Property* (HUP 2003), pp 9-10, fn 32.

society"[54] while at the same time noting that economic analysis provides a "sufficiently firm basis for decisions about 'a little more or a little less' of various ingredients of the patent system."[55] In line with that, many legal and economic studies accept the basic premise that patent rights can work to incentivise innovation and concentrate on the question of the optimal breadth or strength of patent protection[56] – in other words on how well patent systems operate and how their costs can be reduced. Indeed, patent systems on both sides of the Atlantic have faced a lot of criticism in recent years *inter alia* in respect of the patentability criteria, the process of granting/revoking a patent and scope of protection, including discussion of certain practices that are allowed under the patent system (e.g. patent trolls) but could be considered patent misuse. These discussions, however, do not deny patent utility as such, but rather seek to re-design it to incentivise innovation at a lower cost. Some of the more creative studies attempt to redesign the patent system to complement it with an alternative incentive mechanism that would involve lower costs. Wright, for example considered a system of prizes in exchange for commissioned work.[57] Kremer, in turn, contemplated an auction system.[58] Yet, while there exist alternative ways of incentivising innovation through various forms of government inducements (e.g grants, competitions, reimbursement schemes), these public stimuli do not seem to be capable of replacing market-based commercial forces that are at the forefront of the innovation game so as to act as substitutes for patent law.

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54 Fritz Machlup, "An Economic Review of the Patent System" (1958) Study of the Subcommittee on Patents, Trademarks, and Copyright of the Committee on the judiciary, Unites States Senate, Study No 15, p 79, also noting that "[i]f we did not have a patent system, it would be irresponsible, on the basis of our present knowledge of its economic consequences, to recommend instituting one. But since we have had a patent system for a long time, it would be irresponsible, on the basis of our present knowledge, to recommend abolishing it" (p 80).

55 ibid, p 80.

56 See for example Dominique Guellec and Bruno van Pottelsberghe de la Potterie, *The Economics of the European Patent System: IP Policy for Innovation and Competition* (OUP 2007); Richard Gilbert, Carl Schapiro "Optimal Patent Length and Breadth" (1990) 21(1) Rand Journal of Economics 106; F Scherer, "'Nordhaus' Theory of Optimal Patent Life: a Geometric Reinterpretation" (1972) 62 American Economic Review 422; Adam Jaffe, Joshua Lerner, *Innovation and its Discontents: How our Broken Patent System is Endangering Innovation and Progress, and to do about it* (Princeton University Press 2004) (discussing the US patent system).

57 B Wright, "The Economics of Invention Incentives: Patents, Prizes and Research Contracts" (1983) 73(4) American Economic Review 691-707.

58 M Kremer, "Patent Buyouts: A Mechanism for Encouraging Innovation" (1998) CXIII(4) Quarterly Journal of Economics 1137-67.

IV Patent-antitrust intersection through the prism of innovation

The patent-antitrust intersection

22. This section turns to the specific area of application of antitrust policy, which is the object of analysis in this thesis, that is the patent-antitrust intersection. As it will be seen, realisation of a pro-innovation policy by antitrust authorities at this vital intersection between two sets of laws raises some particular issues that go beyond the general controversies discussed above. The account of the objectives of antitrust and the patent system presented above reveals that innovation is a common denominator between these two sets of laws. Still, at first sight at least, antitrust and patent law appear to be in conflict with each other – while one promotes competition and is largely sceptical of monopolistic power, the other grants exclusivity rights that can give rise to a monopoly power. Indeed, this is apparently how the relationship between antitrust and intellectual property is sometimes portrayed by the Court.[59] Yet, according to the European Commission "[t]he fact that intellectual property laws grant exclusive rights... does [not] imply that there is an inherent conflict between intellectual property rights and the Community competition rules."[60] According to this theory of complementarity "both intellectual property rights and competition are necessary to promote innovation and ensure a competitive exploitation thereof."[61]

23. There is a lot to be said about the above approach, especially if one moves away from the portrayal of patents as a species of a monopoly. In fact, as already pointed out above, patents give rise to a monopoly over a market only relatively rarely and their description as a species of property might be more accurate.[62] Equally, however, a step back from the depiction of patent-antitrust interaction as a story of conflict obviously relies on a particular understanding of the role of the antitrust system itself. That understanding sees protection of innovation as one of the aims of antitrust that is realised not solely by promoting price competition. A short-term oriented antitrust policy obviously puts it in conflict with the patent rights.

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59 See Drexl, (n 35), p 37, commenting on the refusal to supply cases.

60 Guidelines on the application of Article 81 of the EC Treaty to technology transfer agreements, OJ C101/04, para 7.

61 ibid.

62 See, however, Hovenkamp (n 17), pp 749-750, noting the problems associated with depiction of patents as a species of property.

24. However, even if one considers the conflict between competition and intellectual property to be overstated,[63] it is hard to deny that there is at least a certain tension between these two sets of legal rules if only because of the way they are applied and the methods they use. Arguably, even this tension could be explained by an inappropriate application of competition law "without regard for the competitive nature of innovation efforts".[64] Yet, even if not conflicting as such, regulatory choices made as a matter of one set of laws might undermine the policy envisaged by the other. Thus, patent-antitrust intersection requires careful management.

Multidimensional nature of the problem

25. From the above it should become clear that the intersection between antitrust and patent law will be approached here in a multidimensional way. This portrayal of the issue is not universally pursued neither by the enforcement authorities nor in the literature.[65] It is, however, a misconception to see antitrust as the sole promoter of competition in this scenario. Yet, the role of patents in creating competition can be easily overseen. Equally, it is an over-simplification to equate patents with innovation for the purposes of antitrust analysis. The patent granting system, with its imperfect system of application examination, allows for granting of patent rights over inventions that do not deserve protection, thus creating 'probabilistic patents' not necessarily reflective of a level of innovative activity. Thus, equating patents with innovation is not only not necessarily reflective of reality but also runs a risk of simplifying the role of antitrust to promoting price competition (since the innovation policy is realised already by the patent system upon this understanding). The multidimensional nature of the problem can be seen already at the level of antitrust analysis regardless of the patent context – through recognition of the fact that competition can occur in respect of various parameters, including innovation, and not just in respect of price.

26. While the innovation perspective is somewhat of a natural prism through which the patent-antitrust intersection is analysed, since it puts the two fields of law on the same

63 See Herbert Hovenkamp, "IP and Antitrust Policy: a Brief Historical Overview" (2005) University of Iowa Legal Studies Research Paper No. 05-31.

64 Ronald A Cass, Keith N Hylton, *Laws of Creation, Property rights in the World of Ideas* (Harvard University Press 2013), p 175.

65 See e.g. Scott Hemphill, "Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem" (2006) New York University Law Review 1553, 1600 (considering that the generalist courts are not equipped to make innovation trade-off assessments and that thus there might be good reasons to focus attention on allocative efficiency); Régibeau and Rockett (n 45) (proponents of the separate treatment approach).

plane, it being a common denominator between the two, it also adds to the multifaceted nature of the discussion. This is due to the fact that innovation policy does not clearly pull in either the direction of requiring strong competitive pressure or operation free of competitive restraints to be able to achieve conditions conducive to innovative activity. An approach whereby undertakings require both a carrot and a stick to be incentivised to innovate appears persuasive, in particular in the context of patent exclusivity where it could be suggested that innovation requires a balance between the rewards provided by patent law and pressure from competition provided by antitrust law. This is indeed the approach that will be applied in this thesis, however with an important caveat. The caveat is that competition is not considered to be one-dimensional, i.e. not limited to competition on the single static parameter of price, but rather to include also competition for innovation (this form of competition for the markets is also known as Schumpeterian competition). Hence, the role of antitrust law in promoting innovation becomes more complex and requires a more complicated balancing act to be performed.

27. Consequently, subjecting competition policy to the requirements of innovation policy does not necessarily equate to establishing a deferential treatment to all activity arising in the patent context. Theoretical scholarship as well as empirical studies suggest that an approach fostering innovation requires a careful balancing of the two policies. It might be that requirements of innovation call for more competitive markets – it does not always mean giving way to monopolist behaviour. Instead, it will require a careful analysis of the effects of a legal position on the incentives of the relevant parties. This, in turn, might require approaching problems not solely from the perspective of a single field of law.

28. Furthermore, prioritising innovation in competition cases with an IP element does not necessarily mean that the innovation objective needs to "win" with other aims of competition law in every case. However, given the value of the gains to be had from innovation relative to the gains from achieving static efficiency, it is likely to often be the case if consumer welfare is to be truly pursued. Additionally, a pro-innovation policy will not always require solutions going against the demands of other competition objectives. The way various objectives can point to solutions going in the same direction will be visible in particular in *AstraZeneca*, a case study discussed in chapter 4.

29. Moreover, the innovation policy itself requires balancing of interests of various types of innovators - breakthrough and follow-on innovators - making the problem even more multidimensional. This sort of balancing of interests is at the core of patent policy, but antitrust authorities, in getting involved in patent issues, might act to rebalance the interests of those two types of innovators.

Regulatory choices

30. Throughout the years antitrust agencies have developed various approaches to the treatment cases with an intellectual property element, not all of these approaches being construed with protection of innovation in mind.[66] The differing approaches could be understood as lying on a spectrum, where on one extreme cases with a patent element are granted total immunity as a matter of competition law (the position of IP dominance) and on the other extreme intellectual property is given no special treatment and is open to challenge whenever it gives rise to market power (the position of absolute competition dominance). In between there are various intermediary solutions.

31. Since patents and antitrust are separate spheres of law, any such solution constitutes a regulatory choice that will inform an interaction between those two fields. In building an antitrust approach to patent matters two questions are potentially relevant: 'if' and 'how'. In deciding on the first question, that is whether antitrust intervention is warranted, one should not be guided solely by the question of formal competence, but also by the need to effectively divide the tasks between different spheres of law in pursuance of an innovation policy. Because of the way in which each patent law and competition law treat issues at the antitrust-patent intersection (the question 'how'), the decision to get involved ('if') might not be neutral from the innovation perspective. Both antitrust and patent law can be accused of undermining or creating obstacles to innovation.[67] Imperfect consideration of the "other side of the equation" might lead to biased solutions that undermine innovation or even the integrity of the patent system.

32. At the same time, it needs to be remembered that these regulatory choices do not appear in the abstract - they are influenced by the institutional and agency set up of the particular legal order. In the EU this is of particular importance, since antitrust and patent law do not operate on the same level in the EU legal order. While EU competition law is grounded in the Treaties, the same cannot be said of patent law,

66 See further ch 10.
67 Herbert Hovenkamp (n 17), p 749.

which is largely outside the scope of jurisdiction of the Court of Justice and largely based on domestic laws of each Member State.[68] Hence, the decisions about the proper division of tasks might be influenced not just by abstract economic considerations, but also by the regulatory set-up. Practical considerations in managing a particular regulatory situation might be influential on the decisions to get involved in patent matters on the part of the competition authorities, as it will be seen in the chapters that follow.

[68] See further ch 9 on the fragmented nature of the patent system.

Part II

Chapter 3

Reverse payment settlements

I Introduction

1. Settlements are a widely used mechanism to end patent disputes – over a third of pharmaceutical patent disputes end up with a settlement.[1] Although they are generally considered to be a legitimate way of ending what is often very complicated litigation, a particular form of settlements, namely reverse payment settlements, attracted attention of the competition authorities on both sides of the Atlantic. Both the Federal Trade Commission (FTC) and the European Commission consider reverse payment settlements that are concluded in the pharmaceutical sector to be anticompetitive because they are said to be causing a delay to generic entry. This position has now also been confirmed by the General Court.[2]
2. Consideration of reverse payment settlements under antitrust law raises difficult questions about the nature of the interaction between antitrust and intellectual property rights. The aim of this chapter is to investigate how the approach to this delicate matter has developed in the context of reverse payment settlements concluded in the pharmaceutical sector, paying particular regard to the policy makers' consideration of questions pertaining to innovation. The purpose is to identify possible deficiencies in the reasoning process, rather than to concentrate on the outcomes reached, since it is the former that will inform the nature of patent scrutiny in future cases.
3. Since the pharmaceutical industry is heavily R&D dependent and relies on competition in innovation, the approach developed to antitrust-patent interaction in respect of reverse payment settlements might have implications for the shape of the whole sector. As a result, one would expect that the innovation dimension would be

[1] Based on data collected by the European Commission during the Pharmaceutical Sector Inquiry (Pharmaceutical Sector Inquiry: Final Report (8 July 2009)): the Report does not provide direct data on the point, but states that out of 698 litigated cases between 2000 and 2007 223 (32 percent) were settled; at that point, however, 326 cases were either still pending or withdrawn, so it is to be expected that the overall figure for settled cases should be higher; data from the US market puts this figure at 47 per cent: Adam Greene, Dewey Steadman, "Pharmaceuticals, Analyzing Litigation Success Rates" (RBS Capital Markets, 2010), p 4, available at: http://amlawdaily.typepad.com/pharmareport.pdf (accessed 1 March 2017).

[2] Case T-472/13 *H. Lundbeck A/S and Lundbeck Ltd v Commission* ECLI:EU:T:2016:449; the judgment of the General Court has been appealed, at the time of writing the decision of the Court of Justice has not yet been rendered: Case C-591/16 P.

carefully scrutinised by the Commission when making its decisions, especially since a sector inquiry conducted by that body identified a decline in the rate of innovation in the pharmaceutical sector in Europe.[3] Yet, as it will be seen in the analysis that follows, the reasoning of the decisions of the European Commission and the General Court's judgment might not be entirely satisfactory in that respect.

4. In exploring the approach to reverse payment settlements this chapter takes a comparative perspective, revealing the extent of the controversy the issue has caused in the US, while the European approach is only just starting to develop. This analysis will be performed with a view to suggesting that the approach currently developing in the EU is at a great risk of taking inadequate account of the innovation dimension in a way that is potentially disruptive to the patent system. The chapter starts off with a section providing background information, introducing the problem of reverse payment settlements together with some of the relevant characteristics of the pharmaceutical sector. As the debate over reverse payment settlements started earlier and achieved a more evolved state in the US, it only becomes logical to begin with the approach developed there (section III). Section IV, in turn, considers the challenges lying before the EU in developing its own approach. The analysis of the decisions taken by the European Commission concentrates on the main issues that are of interest in the context of this inquiry: the level and nature of scrutiny of patent issues, the regulatory take on the interaction between the two spheres, the management of uncertainty inherent in the patent litigation context and consideration of long term effects of the decisions on the incentives of the parties to innovate. It also considers the question whether antitrust involvement could be a reaction to deficiencies of the patent system and whether the patent system could be improved to ease competitive concerns. It will be seen that the Commission decisions are grounded on an implied criticism of the patent system that allows grants of weak patents, which could be read as sending a signal to the patent authorities.

5. The analysis of the decisions reveals that the intrusive standard of antitrust scrutiny is not matched by an in-depth balancing exercise of the diverging policy interests at stake. The competitive examination of reverse payment settlements necessarily involves making assessments in the conditions of uncertainty - a task which reveals

[3] European Commission, Pharmaceutical Sector Inquiry: Final Report (8 July 2009); European Commission Press Release IP/09/1098 of 8th July 2009, "Antitrust: shortcomings in pharmaceutical sector require further action".

the limits of competition tools. The assumptions made as part of competition scrutiny, which might not be reflective of patent reality, might lead to false positive results to the detriment of innovation. Thus, a disregard for the apparent over-inclusiveness of the test might also be taken as a sign of one-sidedness of the approach that does not take into account the impact these decisions might have on the innovative incentive structure in the reverse payment settlement context.

II The pharmaceutical industry and the problem of reverse payment settlements

Originators, generic producers and patent litigation

6. Innovating in the field of pharmaceuticals is an activity requiring huge indivisible investments in R&D.[4] Growing complexity of new drugs increases the amount of resources needed even further.[5] Pharmaceutical companies rely on drug portfolios and blockbuster drugs as not all marketed drugs manage to cover their R&D costs.[6] Bringing a novel medicine to the market is estimated to cost between $800 million and $1 billion.[7] By contrast, bringing a generic drug into the market costs the imitators (i.e the generic producers) as little as $1 million,[8] since they can rely on the abridged marketing authorisation procedure to avoid the burden of clinical trials.[9] The need to obtain regulatory approval means that medicines are comparably easy to copy by imitator companies at relatively small cost since key information about the medicinal

4 Total R&D for prescription medicines in the EU in 2007 was estimated to be around €13,3 billion: Pharmaceutical Sector Inquiry: Final Report (n 2), para 75. The pharmaceutical industry is the most R&D intensive industry sector measured as percentage of net sales: http://www.efpia.eu/tmp/cache/Thumbnail_w700_h700_m_default__uploads_Modules_FactsFigures_graph_hr_8.jpg (accessed 15 May 2016).

5 Irina Haracoglou, "The duty to deal in the Biopharmaceutical Industry: A Follow-On Innovation Perspective", PhD thesis (European University Institute 2005), p 28.

6 ibid, p 29.

7 According to the data collected for the purposes of the Pharmaceutical Sector Inquiry (n 3), para 149; US empirical research points to similar amounts being required for winning an FDA approval (Peter Hutt, *Food and Drug Law* 764 (3rd edn, 2007), although some research suggests even greater amounts are spent if one takes into account the cost of R&D spent on medicines that are eventually unsuccessful (measured over a 15 year period, which is the average time it takes to win an FDA approval: Matthew Herper, "The Truly Staggering Cost of Inventing New Drugs", Forbes (10 Feb 2012)).

8 Emily Morris, "The Myth of Generic Pharmaceutical Competition under the Hatch-Waxman Act" (2012) 22 Fordham Intell.Prop.Media & Ent.L.J. 245, p 262. Another estimate provided by the FDA places the figure between $300,000 and $1mln: Food and Drug Administration, Requirements for Submission of In Vivo Bioequivalence Data; Proposed Rule, 68 Fed. Reg. 61 640 (29 Oct 2003) at 61645; the Sector Inquiry Report (n 3) does not provide data on the cost of generic entry in the EU, but it is expected to be of a similar magnitude.

9 Under the centralized procedure; brand producers can however take advantage of up to 11 years of data exclusivity:http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004018.pdf (accessed 1 March 2017).

product can hardly be kept secret by the originator.[10] This is where the incentivising role of patent protection becomes crucial.

7. Although patent linkage[11] is unlawful in the EU,[12] the way the authorisation procedure is built makes it difficult for generic producers to escape unnoticed with a patent infringement, especially one concerning a compound.[13] In the EU there are two ways to obtain authorisation, which is required to put a medicinal product on the market: either at the EU level through the European Medicines Agency, which provides for a harmonised procedure; or at a national level, leading to mutual recognition.[14] Authorisation is granted on the basis of scientific criteria pertaining to quality, efficacy and safety of the medicinal products and, in case of the originator producers, it requires providing extensive data from the clinical trials.[15] Original applications benefit, however, from marketing and data exclusivity for a period of time, which is another way of protecting an invention operating in parallel with patent/SPC protection that prevents the generic producers from using the abridged procedure while the period of protection lasts.[16]

8. Breakthrough innovation achieved by the originator companies as enabled by patent protection has a significant positive effect on consumers' well-being. New medicines contribute to patient health. Resulting increased life expectancy can in turn be translated to a money equivalent – in the US that was estimated to amount to $1.2mln

10 Henry Grabowski, "Patents, Innovation and Access to New Pharmaceuticals" 5 J.I.E.L. 849 at 851.

11 The practice of linking of granting of regulatory approval, such as of granting of a marketing authorisation, to the status of the of the patent (application) owned by the originator in respect of the reference product.

12 Pharmaceutical Sector Inquiry: Final Report (n 3), para 872, relying on article 81 of Regulation (EC) 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency of 31 March 2004 OJ L 136/1 and article 126 of Directive (EC) 2001/83 on the Community code relating to medicinal products for human use of 6 November 2001 OJ L 311.

13 A full list of authorised medicinal substances and those under evaluation is publicly available at: http://www.ema.europa.eu/ema/index.jsp?curl=pages/includes/medicines/medicines_landing_page.jsp&mid= (accessed 1 March 2017).

14 Council Directive 65/65/EEC requires all Member states to enact laws to ensure that new medicinal products are marketed only after receiving authorisation from a regulatory body. An application submitted through a centralised procedure in the form of a common technical document (CTD) is considered by the Committee for Medicinal Products for Human Use composed of national experts, which sends its opinion to the European Commission which makes the final decision after consulting the Member States.

15 For more details on the marketing authorisation procedure see the Pharmaceutical Sector Inquiry Report (n 3), para 298 ff.

16 Art 10 of the Directive 2004/27/EC and in art 14(11) of the Regulation 726/2004.

per person over the twentieth century.[17] Production of bioequivalents[18] by generic producers also contributes to consumers' well-being by drawing prices down through introduction of competition following patents' expiry.[19] Generic producers also play an instrumental role in challenging patents, thus contributing to discovery of invalid patents which do not warrant protection.

9. Patent litigation, however, can be extremely costly and in many cases inherently uncertain. Thus, it often ends with a settlement. A settlement might be considered an amicable way of ending wasteful litigation that imposes a cost on the society, thus a phenomenon that is desirable also from the public perspective. Generally speaking, three possible settlement scenarios can arise: 1) the parties to a settlement might simply agree to abstain from further action and part ways, or 2) one of the parties might (impliedly) accept (non-)infringement and agree to pay damages commensurate with the loss of the other party, or 3) they might agree on a mutually agreeable solution in circumstances where they are both convinced of the strength of their case. Only in the third scenario both of the parties to a dispute remain convinced that they are in the right. In these latter circumstances a value transfer accompanying the settlement might serve to bridge the expectation gap between the parties. Arguably, one particular form of those settlements are reverse payment settlements.

Forms of reverse payment settlements in the pharmaceutical industry

10. Reverse payment settlements, sometimes also called pay-for-delay settlements, are characterised by cash or value transfers from the originator company to the generic producer usually in return for the latter acknowledging the patent as valid and abstaining from entering the market.[20] The name reverse payment settlements comes from an assumption that normally payments are expected to flow the other way round

17 Kevin M. Murphy, Robert H. Topel, "The Value of Longevity" (2006) 114(5) J. Pol. Econ. 871-904, p 872 ("From 1970 to 2000, gains in life expectancy added about $3.2 trillion per year to national wealth").

18 In the European Commission's Pharmaceutical Sector Inquiry: Final Report (n 3) generic drugs are defined as "a medicinal product which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as a reference (originator) medicinal product and whose bioequivalence with the reference medicinal product has been demonstrated...".

19 European Commission, Pharmaceutical Sector Inquiry: Final Report (n 3), para 212: on average prices dropped by 25 per cent two years after brand name's loss of exclusivity following generic entry for the medicines studied.

20 The pay-for-delay settlements terminology will not be used here, due to the fact that it could be read negatively as implying presumed anticompetitive intent of those settlements. Since one of the assumptions of this chapter is that an answer to the question whether these settlements are anticompetitive cannot be reached without careful analysis, any such predetermination should be avoided.

– i.e. from the generic producer to the originator as compensation for the alleged infringement. Schildkraut has argued, however, that in most patent settlements consideration in some form is likely to be transferred from the patent holder to the alleged infringer.[21] As a result, he considers the term reverse payment settlement to be pejorative. Indeed, even a phrase "value transfer" might be considered pejorative.[22] For lack of a better phrase and to follow the widely used terminology, the term reverse payment settlements will be used throughout this thesis.

11. The principal problem with reverse payment settlements as perceived by the competition authorities is that they can be disguised agreements not to enter the market in return for payment. In absence of an underlying patent those agreements would clearly be anticompetitive and considered hardcore cartels. However, the presence of a patent dispute complicates matters. If the patent under dispute turned out to be valid, then the behaviour would fall within the exclusionary scope of the patent and could not reasonably be said to be delaying generic entry. It is the potential invalidity of patents that makes those settlements suspicious. This, however, remains an object of uncertainty in absence of a ruling from a patent court.

The risks involved

12. Condemning reverse payment settlements is not without its risks. A risk of achieving false positive results equates not only to condemnation of genuine attempts at solving a dispute, but also entails negative consequences for the system of incentives directed at promoting innovation. A model developed by Dickey, Orszag and Tyson shows that in a situation where an expectation gap as to the outcome of the dispute exists between the parties, it cannot be simply assumed that the parties will conclude a settlement on different terms.[23] In those circumstances a payment of a premium to the alleged infringer to discontinue litigation can be seen as a normal feature of settlement negotiation.[24] In those circumstances it is also a fallacy to think that a continuation of litigation would always be beneficial for the consumer[25] just as much as it would be a

21 Marc G Schildkraut, "Patent-splitting Settlements and the Reverse Payment Fallacy" (2004) Antitrust Law Journal 1033 at 1033.

22 Pat Treacy and Sophie Lawrence, "Intellectual Property Rights and out of court settlements", p 290 in Steven Anderman and Ariel Ezrachi, *Intellectual Property and Competition Law: New Frontiers* (OUP 2011).

23 Bret Dickey, Jonathan Orszag and Laura Tyson, "An economic assessment of patent settlements in the pharmaceutical industry" (2010) 19 AHTHL 367.

24 ibid, p 389.

25 As shown by the model developed by Dickey et al (n 23).

fallacy to think that any additional surplus going to the pocket of the patent holder is a consumer surplus lost by the same amount.[26] Consumers are believed to be entitled to the surplus resulting from an earlier generic entry (which is in no way certain in the reverse payment settlement context),[27] but it is easily forgotten that this surplus would not have existed but for the innovative effort of the originator company. If the incentive to innovate is diminished, the product market might not even come into existence, rendering any discussion of eventual consumer surplus meaningless.

13. Restricting the options available to the parties to a patent dispute through antitrust limitations might work as a barrier to exit which in turn translates to a barrier to entry.[28] Inability of escaping patent litigation reduces the value of exploiting inventions. However, it is not just the outcome of antitrust scrutiny, but also the fact of antitrust scrutiny itself that might affect the incentives to innovate. It has been argued by Hylton that "the increasing burden of antitrust litigation and [antitrust] regulatory expropriation probably has worked to dampen incentives to innovate."[29] This should be particularly true if a wide definition of a value transfer is adapted, leading to many settlements potentially falling under antitrust scrutiny.

Where is the innovation flowing from?

14. In the pharmaceutical sector, it is the originator company which is taken to be the source of innovation. In fact, the name originator and innovator are sometimes used interchangeably. Although the role of originators in bringing innovation into the market is undeniable, they are not the sole source of innovation. While perhaps not involved in the process of breakthrough innovation, generic producers play a role in the process of incremental (follow-on) innovation.

15. Generic producers may contribute to the innovation process by working on improving the formulation, dosage, methods of delivery or processes that lead to creation of bioequivalent medicinal products. They engage in patent activity in respect of these

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26 Keith N Hylton, "A Unified Framework for Competition Policy an Innovation Policy" (2013) Boston University School of Law Working Paper 13-55, p 13; the contrary is claimed by the Commission in the reverse payment settlement decisions it took: *Lundbeck* (n 69), para 646; *Servier* (n 55), para 1152.

27 It is not universally accepted that in the circumstances consumers should be entitled to an outcome of avoided litigation. This view is questioned by Scott Hemphill, "Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem" (2006) New York University Law Review 1553, p 1576.

28 Marc G Schildkraut, "Patent-splitting Settlements and the Reverse Payment Fallacy" (2004) Antitrust Law Journal 1033, p 1049, relying on Baumol (William J Baumol, John C Panzar and Robert D Willig, *Contestable Markets and the Theory of Industry Structure* (Harcourt Brace Jovanovich Publishers 1982).

29 Hylton (n 26), p 12.

inventions in the same way as the originator companies. So, the distinction between originator and generic producers might not be as straightforward as it might at first appear. The mere existence of generic producers can also be said to contribute to the process of innovation because it incentivises originator producers to continue to invent new medicinal products following the expiry of patents protecting the original product.

16. According to the Commission's Sector Inquiry Report, R&D costs amount to 7 per cent of the generic producers' turnover (compared to 18 per cent by originator companies).[30] In real money terms, however, the differences in investment in R&D might be more significant, given the differences in size of originator and generic producers.[31] Moreover, R&D can only be used only as a proxy for innovation here, since there are more elements to the innovation process than just investments in R&D and since the amount of R&D investment does not directly correspond to the level of innovation. On the whole, it can be said that the pharmaceutical sector is much less about incremental innovation than other sectors.[32]

17. Still, the fact that innovation does not simply flow in a single direction from the originators could complicate somehow the analysis of reverse payment settlements. However, it could be argued that a potential impact of possible false positive findings on the originators' incentives to innovate is far more significant than possible effects of an opposite finding on the generic producers' incentives. The position of the originators should come first, because incremental innovation by generic producers is dependent on breakthrough innovation by the originators. To put it simply, there would be no incremental innovation by the generic producers without breakthrough innovation by the originators. Generic producers' position is more significant here as a source of pressure on the originators to continue the innovation game.

30 Pharmaceutical Sector Inquiry: Final Report (n 3), pp 40 and 32 respectively; the figure for originator companies jumps to 40 per cent for biopharmaceutical companies (para 56) Note that the scope of the Report is limited to a selected sample of prescription medicines.

31 According to the Commission's Sector Inquiry Report (n 3), the EU turnover of top ten originator companies in 2007 was 58,652,717,000 (p 26), compared to 9,940,683,000 of top ten generic in the same period (p 37).

32 See for example Hemphill (n 27), pp 1564-1565.

III The US experience

How the approach developed?

18. Patent settlements have been on the agenda of the antitrust authorities in the US for some time now. The first case to reach the Supreme Court was the *Standard Oil* case from 1931.[33] That case, however, concerned a settlement consisting of cross-licensing agreements. A surge of antitrust cases concerning reverse payment settlements started to reach the courts in the 2000s. The FTC has played a leading role in bringing those cases before the courts. Also, starting from 2002, it has conducted a series of studies on the topic, concluding that those agreements have a strong anti-competitive potential.[34]

19. The 2002 Study had a wider scope and also considered the operation of the regulatory framework. It did not attempt an in-depth analysis of neither the anticompetitive effects of reverse payment settlements nor the implications of such finding on the IP system of protection. The 2010 study, on the other hand, condemned those settlements in very outright terms and estimated that they cost American consumers $3,5 billion every year. This conclusion appears to be founded on a (questionable) finding that those settlements on average prevent generic entry for 17 months more than agreements without payments.[35]

20. The 2010 study concentrates on short-term effects on price, without giving any serious thought to long term effects or the consequences for the patent system or incentives to innovate. It considers the perspective of generic producers and their role in imitating the invention (diffusion process – third stage in the innovation process), without considering the position of the originator (responsible for first and second stage of the innovation process). Thus, the potential cost of loss of breakthrough innovation through diminished incentives, which admittedly is much more difficult to quantify, was not considered at all. Unfortunately, this one-sided perception of the dynamics of the situation informed the FTC's approach to reverse payment settlements.

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33 *Standard Oil Co. (Indiana) v. United States*, 283 U.S. 163, 51 S.Ct. 421, 75 L.Ed. 926.

34 Federal Trade Commission, "Generic Drug entry Prior to Patent Expiration: An FTC Study (July 2002); Pay-for-Delay: How Drug Company Pay-offs cost consumers Billions" (January 2010); "Authorized Generic Drugs: Short Term Effects and Long Term Impact" (August 2011).

35 It is considered questionable because it might be unjustified to assume that another settlement allowing for earlier entry would be concluded in absence of a reverse payment settlement or that a patent would be held invalid if the litigation continued.

21. Despite the FTC's strong stance against reverse payment settlements, the issue proved to be controversial already at the level of competition authorities. The US Department of Justice did not share the FTC's approach to reverse payment settlements.[36] While contemplating a possibility of settlement agreements having a potential to be anti-competitive, for the Department of Justice a mere existence of a reverse payment settlement was not enough for a finding of an anticompetitive conduct. When the FTC filed a *certiorari* to bring the question before the Supreme Court following the *Shering-Plough* decision, the Department of Justice went so far as to oppose it in a brief by the Solicitor General.[37] This disagreement between the two authorities illustrates well the controversy and the difficulty of the issue at play.

22. A similar non-uniformity of approach could be seen at the court level. The cases varied from findings of per se unlawfulness (*Cartizem CD*)[38] to per se legality (*Schering-Plough*).[39] In *In re Tamaxifen*[40] the 2nd circuit court applying the scope of the patent principle decided that those agreements can be anticompetitive only if extending beyond patent duration or if shown to be a sham. Following a few years of continued uncertainty caused by inconsistent judgments, the FTC finally managed to bring a case before the Supreme Court – the *Actavis* case was decided on 17 June 2013, two days before the first European Commission's decision on the point.

The Actavis case

23. The Supreme Court in the *FTC v Actavis* broke with the scope of the patent principle and held in a 5-3 decision that the reverse payment settlement in question was "not immune from antitrust attack, even if the agreement's anticompetitive effects fell within the scope of the exclusionary potential of the patent."[41] However, this should be assessed using the rule of reason standard and not, as argued by the FTC, per se illegality. The Court's lack of conviction that reverse payment settlements are obviously anticompetitive essentially means that the burden of proof will be on the FTC to show in each case that an agreement is anticompetitive. This in turn, at least

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37 Petition for writ of Certiorari to the United States Court of Appeals for the Eleventh Circuit, Brief for the United States as Amici Curiae, *FTC v Schering-Plough Corp., et al*., 548 US 919 (2006).

38 *In re Cartizem CD Antitrust Litig*. 105 F. Supp. 2d 618 (6th Cir. 2002).

39 *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005).

40 *In re Tamoxifen Citrate Antitrust Litig.*, 429 F.3d 370 (2d Cir. 2005).

41 *FTC v Actavis, Inc., et al.* 133 S.Ct. 2223 (2013).

potentially, opens the doors to a fuller analysis of the effects of reverse payment settlements, including long term effects.

24. In its opinion the Court provided five reasons why the FTC should be allowed to bring cases before courts alleging anticompetitiveness of reverse payment settlements. In doing so, it acknowledged the anticompetitive potential of reverse payment settlements and expressed a belief that competition scrutiny should not prevent settlements in general as well as that it should be administrable. At the same time, it offered very limited and vague guidance on the precise dynamics of such competition assessment and the relevant considerations in deciding cases like the one at issue in *Actavis*.

25. Importantly, the Court thought that the competition assessment would not normally require an assessment of validity of the patent. Instead, it was prepared to rely on the patent holder's perception of the strength of its patent as inferred from the size of the payment and from there establish anticompetitive intent.

26. It also considered the fact that the patent holder has no right to damages (because the potential infringer has not entered the market due to the way the US regulatory framework is constructed) to be a relevant factor, making the payment more suspicious. Furthermore, it considered that patent holders should negotiate to allow generics into the market sooner, rather than paying them money. All of these reveal a rather sceptical approach to settlements involving value transfers. At the same time, desirability of settlements in general (reflecting the public interest in putting an end to complex and expensive litigation) was emphasised as a strong consideration by the Supreme Court.

27. The decision of the Court also contains some direct discussion of the question of interrelation between antitrust and intellectual property. One passage from the Court's judgment deserves particular attention: "it would be *incongruou*s 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".[42] At first sight, this might be seen as a surprisingly strong statement on an issue that has been previously approached with great caution. It might be interpreted as trumping patent policy considerations in light of antitrust policies. It might, however, be an overstatement to say that it is pronouncing a supremacy of competition law over

[42] Emphasis added.

intellectual property. This is so since in listing traditional competition factors according to which reverse payment settlements should be assessed, the majority opinion notes potential offsetting legal considerations, including "those related to patents". However, neither the exact nature of such consideration nor its implications are elaborated in the judgment. Consequently, it becomes unclear what significance the existence of a patent has in the circumstances. It would appear that the US supreme Court is in effect prepared to re-evaluate the balance struck as a matter of patent policy in light of antitrust goals, while these goals might include consideration of the competition conditions created by patents. The resulting system is, however, likely to push the balance towards innovation through competition, rather than innovation through exclusivity.

28. The approach of the Court was strongly opposed in the dissenting opinion from Chief Justice Roberts (with whom Judge Scalia and Thomas concurred). The dissenting decision is interesting for it highlights the problems with applying the Court's approach. In view of the dissenting judges, patent validity would be an obvious defence to be used by the patent holder in a competition case. They thought that the majority was "unresponsive to the basic problem that settling a patent claim cannot possibly impose unlawful anticompetitive harm if the patent holder is acting within the scope of a valid patent and therefore permitted to do precisely what the antitrust suit claims is unlawful." Chief Justice Roberts considered the approach of the majority an inappropriate encroachment on patent policy which he compared with crossing a Rubicon that was never crossed before.

29. The dissent took a completely different stance on the interaction between competition law and intellectual property. According to Chief Justice Roberts, there is scope for antitrust assessment only if the agreement in question goes beyond the scope of patent protection. In that respect, he considered settling a patent case to be an activity within the scope of patent protection, unless the dispute is proven to be sham or the patent to be obtained by fraud. To him the Court's approach constituted an undesirable departure from the statute and an encroachment on the sphere of patent law. A passage from the dissenting opinion saying that "the majority seems to think that even if the patent is valid, a patent holder violates the antitrust laws merely because the settlement took away some chance that his patent would be declared invalid by a court" highlights the potential for false positive results created by the judgment. In this model the uncertainty pertaining to the patent litigation context favours the patent holder by

shielding him from antitrust liability. Although the approach of the dissenting judges is based on the consideration of the inherent limitations of antitrust authorities in scrutinising patent issues, it might lead to false negative results.

30. The Supreme Court's pronouncement on reverse payment settlements raised considerable interest from various interest groups as can be illustrated by the number of *amici curiae* briefs submitted for the Court's consideration. In total 27 amici briefs were filed with the Court, a number of which came from IP organizations.[43] The majority of the amici briefs (including all IP organizations) opposed the FTC's approach to reverse payment settlements, pointing to insufficient proof of the anticompetitive effects of those settlements as well as the effect on the IP system and incentives to innovate. Given, the strength of some of the arguments raised in the briefs, it might be disappointing that the Court did not consider in more detail the implications of its decision on innovation. The engagement of IPR bodies in the case could be taken as an attempt at signalling back that antitrust might be undermining patent policy. As such it constituted an opportunity for the Court to see the other side of the argument, not simply as presented as part of the defence.

Where next?

31. The *Actavis* case can be seen as a landmark case for breaking with the well-established "scope of the patent" principle. Consequently, the case might have wider ramifications for the approach to any antitrust cases raising IP related matters. At the same time, it remains to be seen how the standard it set will be applied in practice. Cases that followed the Supreme Court's pronouncement have already highlighted how much has been left unresolved by the ruling and how parties might try to circumvent it.[44] This continued uncertainty might be even worse news for the originator firms than outright condemnation of reverse payment settlements.

32. Lack of clarity surrounding the question of application of the *Actavis* judgment already led to numerous court actions reaching varying results. The lower courts were left to resolve the most basic questions concerning reverse payment settlements, including what constitutes a reverse payment settlement. Since the Supreme Court judgment in *Actavis* suggested that reverse payment settlements might be limited to

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43 These included the American Intellectual Property Law Association (AIPLA), Intellectual Property Owners Association and New York Intellectual Property Law Association.

44 See Ankur Kapoor and Rosa M Morales, "Courts' Prescription for Reverse-Payment Settlements Still Unknown Almost a Year After FTC v. Actavis" (2014) 4(2) CPI Antitrust Chronicle.

cash payments, the lower courts were left to consider whether other value transfers, in form of for example distribution or licensing agreements, could also be potentially anticompetitive. The Court of Appeals (Third Circuit) held in the *Lamictal* case (concerning a no-authorised-generic agreement) that reverse payment agreements need not involve cash transfers, thus rejecting an earlier district court narrow reading of *Actavis* limiting it to cash payments.[45] The effect of *Actavis* might have been to push companies to construct more elaborate settlement agreements to disguise their true intentions.[46] As a consequence, the lower courts are yet to test the limits of the understanding of a potentially anticompetitive value transfer. If carelessly applied, the *Actavis* case could open floodgates to litigation, which would have negative consequences for R&D in the pharmaceutical industry.[47]

33. Yet, many cases that reached the courts following *Actavis* failed for various reasons. In a reversed burden of proof situation under the rule of reason the plaintiffs struggle to prove causation, as was the case in the *Nexium* and *Wellbutrin XL* litigations.[48] Both of these cases are also interesting for the type of value transfers which were alleged to be anticompetitive. In the latter case, the settlement, apart from containing a no authorised generic provision, also included an early entry clause and sublicenses for other patents and so was actually considered pro-competitive, since it actually created generic entry.[49] In the former case, on the other hand, the jury found that AstraZeneca made a "large and unjustified" payment with a settlement agreement that included an no authorised generic provision, licences for unrelated medicines, acceleration clauses (allowing for an immediate entry if another generic entry occurs) and acceptance of low damages in an unrelated patent litigation.[50] The inclusion of that last element of the agreement, in particular, within the calculation of the value transfer signifies that the court is willing to go into questions that are usually reserved for the courts dealing

45 *King Drug Co. of Florence Inc. v SmithKlineBeecham Corp. d/b/a GlaxoSmithKline*, No 14-1243 (3d Cir. June 26, 2015) ('Lamictal').

46 Damien Geradin, Douglas Ginsburg, Graham Safty, "Reverse Payment Patent Settlements in the European Union and the United States" (2015) George Mason Law & Economics Research Paper No. 15-38, p 8.

47 Daryl Lim, "Reverse payments - life after Actavis" (2014) 45(1) IIC 1-5, p 3.

48 *In re Nexium (Esomeprazole) Antitrust Litigation*, 2015 U.S Dist. LEXIS 102 102115 (D.Mass. July 30, 2015); *In re Wellbutrin XL Antitrust Litigation*, No 08-2431, 2015 U.S.Dist. Lexis 127373(E.D. Pa. Sept 23, 2015).

49 Ankur Kapoor, Rosa M Morales,"'Reverse-Payment Cases in 2015" (2015) 12(1) CPI Antitrust Chronicle, p 5.

50 Seth C Silber, Jeff Bank, Courney Armour, Kellie Kemp, Brendan Coffman, Ryan Maddock, "Pharmaceutical Antitrust Litigation in 2015-Settlements, Product Hopping, and REMS" (2015) 12(1) CPI Antitrust Chronicle, p 4.

with patent matters or otherwise are left to the parties to freely agree upon as an expression of negotiation. While an agreement of this sort could be an attempt to hide a cash transfer, it is hardly an unavoidable conclusion. In absence of direct evidence that this was the parties' intention, establishing that damages were unreasonably low is not an easy task. In *Nexium* itself the parties provided contradictory expert opinions on that point.[51] Since *Nexium* also suggests a very far reaching understanding of a value transfer, the patent holders might become wary of antitrust liability in respect of an even greater number of situations, further limiting their access to settlements even where this is not warranted.

34. It is not just private parties that intensified their litigation activity in the aftermath of *Actavis*, the FTC also remains actively involved in litigation, either by bringing cases itself or by submitting amici briefs in private cases. Apart from continuing to actively investigate patent settlements,[52] the FTC continues to shape antitrust policy in that area also by settling suits. Most significantly, it has settled a suit against Cephalon (also investigated by the European Commission).[53] Under the terms of the settlement the defendant, Teva, agreed not only to create a $1.2 billion fund aimed at compensating the purchasers of its drug, Modafinil, but also not to enter into any reverse payment settlement agreements without FTC's approval. Teva being the largest generic manufacturer in the world,[54] the agreement constitutes a significant victory for the FTC. This way the FTC might be able to achieve through the back door what it did not manage to do before the Supreme Court – i.e. bring reverse payment settlements to an end even though the Court has not found them to be presumptively illegal/anticompetitive. If it succeeds in doing that, its actions might have a negative effect on consumer welfare, since it will thus also eliminate agreements that can be pro-competitive. The decreased availability of settlements might in turn create unfavourable conditions for investment in the pharmaceutical R&D and have a chilling effect on innovation. Nonetheless, the FTC continues to be convinced that the need to secure chances for generic entry overrides these considerations.

35. While the controversy over reverse payment settlements continues in the US, partially because of the difficulty associated with establishing a viable counterfactual in the

51 Geradin et al (n 46), p 8.

52 Seth Silber, Jonathan Lutinski, Ryan Maddock, "'Good Luck' Post-*Actavis*: Current State of Play on 'Pay-for-Delay' Settlements" (2014) 11(2) CPI Antitrust Chronicle, p 7.

53 European Commission Press Release IP/11/511 of 28th April 2011 "Antitrust: Commission opens investigation against pharmaceutical companies Cephalon and Teva".

54 Sector Inquiry (n 3), para 95.

conditions of uncertainty associated with patent litigation, it shows how difficult it might be distinguish between legitimate from wrongful conduct. This is so also in light of different value transfers that might occur in the settlement context. Too broad scope of liability might have a chilling effect on innovation by unjustifiably limiting options of avoiding litigation. Although the Supreme Court was not persuaded that reverse payment settlements are obviously anticompetitive, the *Actavis* case changed the regulatory balance between antitrust and patent policies, giving an upper hand to antitrust. This in itself need not be a negative development from the innovation perspective, however, it appears that the Court's analysis of the situation might not have been truthful to the dynamics of the patent system. This is visible in particular in presuming weakness of the patent from the size of the payment. Any resulting rebalancing of patent policy that occurs without a proper consideration of the implications thereof might have negative consequences for innovation policy.

36. The US experience with reverse payment settlements could be thus seen as a warning sign and a valuable source of information on the risks involved for the European Commission in developing its own approach. The Commission in its decisions, however, rejected arguments drawing on the US case-law: partially on the formal ground that it is not bound by it and so it neither needs to accept those arguments nor is it obliged to reason their rejection, and partially because of the significant differences between the regulatory frameworks in the US and the EU.[55] The General Court, on the other hand, referred to the *Actavis* case to support its position,[56] while also noting that the Commission did not need to refer to the legal tests adapted by a third country.[57] Could the differing US regulatory framework, however, be a justification for antitrust involvement?

The regulatory framework – the intricacies of the US system

37. One of the distinguishing features of the US pharmaceutical sector is its regulatory framework. The Drug Price Competition and Patent Term Restoration Act 1984,[58] more commonly known as the Hatch-Waxman Act, has been influential in shaping the antitrust approach to reverse payment settlements. Hemphill has gone so far as to

55 Case AT.39612 - *Perindopril (Servier)* C(2014) 4955 final, para 1199.
56 *Lundbeck* (n 2), para 353.
57 *Lundbeck* (n 2), para 511.
58 21 U.S.C. § 355.

argue that it is key to understanding the US approach.[59] As it will be seen below, the Hatch-Waxman Act has the effect of affecting the incentives of the parties and widens the potential for anticompetitive conduct through the use of settlements, thus providing an additional reason for viewing reverse payment settlements as anticompetitive. It could also described as rebalancing the default patent policy position that favours innovation over consumer access specifically in the pharmaceutical context.[60]

38. The Hatch-Waxman Act provides for a simplified market authorisation procedure for generic producers, who only need to demonstrate that their medicinal product is using the same active ingredients and is bioequivalent to an already authorised originator's medicine. This Abbreviated NDA (New Drug Application) procedure spares the generic producers the time and cost associated with clinical trials required of an NDA procedure that the originators need to undergo. As part of the ANDA process that seeks authorisation prior to patent expiry, generic producers are required to file a paragraph IV certification, in which they assert that their product does not infringe on the originator's patent or that the patent is invalid. The originator then has 45 days in which to file suit against the generic producer in court, in which case the authorisation of the generic drug is stayed for 30 months or until judgment on patent validity/infringement is given, whichever is earlier.[61] If however the generic producer prevails in court, and the patent is held invalid or not infringed, it is then rewarded with a 180 day period of exclusivity to market its generic product. The exclusivity period is available to the first challenger only. Thus, the regulatory framework is designed to encourage challenges to patents by providing an additional incentive in form of limited exclusivity offered to the generic producer.

39. However, it has also been suggested that it makes (reverse payment) settlements more attractive for the patent holders since other generic producers have less incentive to challenge the patent. So, from the originator's perspective a settlement with the first challenger can be taken as effectively removing the risk of an early generic entry. However, the mere fact that other generic producers cannot expect the extra reward for their challenge, should not suggest that the motivation to bring a challenge against a

59 Hemphill (n 27) 1553.

60 Hemphill (n 27), p 1597; the characterisation of the balancing exercise as one in which innovation and consumer access are put on the opposing sides is, however, characteristic of the separate treatment approach (see further ch 10).

61 Unless the patent expires earlier.

patent is removed. Indeed if that was the case, then it would be hard to explain challenges to patents in other countries where the respective regulatory frameworks do not provide for an extra reward.

40. However, due to the operation of the exclusivity period, second generic challenger's application will be considered effective only after 180 days from the first commercial marketing by the first generic ANDA applicant, subject to forfeiture of the exclusivity.[62] In case of a settlement between the originator and the first filer, the most likely causes of forfeiture are failure to market,[63] withdrawal of application or a final finding by the FTC or court that the agreement is anticompetitive. Each possibility can be associated with a significant delay. The above, however, would suggest that the problem of generic delay lies with the regulatory framework and in particular the mode of operation of the exclusivity period, rather than reverse payment settlements. Reform of the forfeiture provisions to include settlements (and not just settlements conclusively and authoritatively determined to be anticompetitive) would eliminate the problem for which reverse payment settlements as such cannot be blamed.

41. Yet, if the Hatch-Waxman Act is indeed an enabling platform for the conclusion of settlements that are of an anticompetitive nature, then it could be argued that the approach to reverse payment settlements that the European Commission has adapted might be unjustified given the absence of equivalent regulation in the EU. It has been argued by Hemphill that the Hatch-Waxman Act "embodies a specific congressional judgment about the proper balance between competition and innovation in an industry".[64] According to him, it does not matter what stance on patent settlements is taken in other sectors as a matter of a general patent policy, since the Hatch-Waxman Act amends this position for the pharmaceutical sector. This is significant for it could suggest that the US approach to reverse payment settlements should be seen as an industry-specific solution which possibly should not be applied elsewhere. This interpretation bases the intervention of the particular congressional judgement made through the Hatch-Waxman Act that favours litigated challenges through the use of patent linkage and encouragement of generic challenges through provision of

62 21 U.S.C. 355(j)(5)(B)(iv).

63 In case of a failure to market, second applicant can proceed with their application following 30 months from first application.

64 Hemphill (n 27) , p 1557.

additional rewards.[65] In that sense, reverse payment settlements could be said to be obstructing the purpose of that Act.

42. If indeed the US problem with reverse payment settlements cannot be solved at a level of generality, then it can be only of limited guidance for the European competition authorities. If anything, it would suggest that the European approach should be more lenient to reverse payment settlements than the US approach. However, the arguments put forward by the FTC and the Supreme Court in *Actavis* are not necessarily tied to the particular regulatory framework in which the US pharmaceutical sector operates.

IV Developing a European approach

43. Unlike in the US, in the EU the issue of reverse payment settlements has not surfaced at the Commission level until very recently. At the beginning of 2008, as "a response to indications that competition in pharmaceutical markets in Europe may not be working well"[66] and perhaps also inspired by the FTC's approach, the Commission has launched a sector inquiry into the pharmaceutical sector. That was quickly followed by an opening of formal investigations into settlements concluded by several pharmaceutical companies.[67] To date, these resulted in two prohibition decisions: one concerning settlements concluded by Lundbeck and one concerning settlements agreed by Servier.[68] The position the Commission took in *Lundbeck* has now also been

65 In connection to that, one more feature of the Hatch-Waxman Act deserves particular attention. Since generic producers in the US challenge patents through paragraph IV certification, rather than by entering the market, they do not risk having to pay huge damages if they fail in litigation. This significantly affects the generic producers' incentives to challenge patents. It has been shown that generic producers are prepared to challenge patents even if their chances of success are as minimal as 1,3 per cent (The figure depends on the size of the market for the brand product; 1,3 per cent chance applies to nearly 90 per cent branded drug sales: Kelly Smith, and Jonathan Gleklen, "Generic Drugmakers Will Challenge Patents Even When They Have a 97% Chance of Losing: the FTC Report that K-Dur Ignored" (2012) 9(2) CPI Antitrust Chronicle. This skewed incentive arrangement could explain the flow of consideration in a reverse payment settlement.

66 European Commission Press Release IP/08/49 of 16 January 2008 "Antitrust: Commission launches sector inquiry into pharmaceuticals with unannounced inspections".

67 European Commission Press Release IP/12/835 of 30 July 2012 "Antitrust: Commission sends Statement of Objections on perindopril to Servier and others"; European Commission Press Release IP/12/834 of 25 July 2012 "Antitrust: Commission sends Statement of Objections to Lundbeck and others for preventing market entry of generic antidepressant medicine".

68 Case AT.39226 - *Lundbeck* C(2013) 3803 final; Case AT.39612 - *Perindopril (Servier)* C(2014) 4955 final; Some commentators also include the agreement between Johnson & Johnson and Novartis concerning fentanyl in the same group of decisions. However, that decision concerned a co-promotion agreement rather than a patent litigation settlement and as such is not included in the analysis that follows (Case AT.39685 - *Fentanyl* C(2013) 8870 final).

confirmed by a judgment of the General Court.[69] The two decisions take virtually the same approach to reverse patent settlements, with only two notable differences: despite considering the practice to be anticompetitive by object, the *Servier* decision included an additional effects analysis under article 101 and, moreover, it considered the settlement practice pursued by Servier also to be anticompetitive under article 102, not just under article 101. While the General Court confirmed that reverse payment settlements are anticompetitive by object and generally followed the Commission's approach, its reasoning brought the issue closer to the *Actavis* case, as it will be seen below. Because of their similarities, the decisions are examined side by side. Before moving on to analysing the approach to patent settlements the Commission and the General Court took in those cases, however, the treatment of those in the sector inquiry report warrants some attention.

The sector inquiry and the monitoring reports

44. The pharmaceutical sector inquiry conducted by the Commission identified settlements with a value transfer as one of the potential problem areas, which needed to be investigated further.[70] Throughout the sector inquiry report the Commission emphasised that it was not meant to provide competition guidance,[71] yet its position in respect of reverse payment settlements was quite explicit. Although the Commission stated that it was not yet in a position to offer policy guidance on the point,[72] it still openly stated that "patent settlements with a value transfers [sic] from the originator company to the generic company can be used to eliminate competition if the generic company agrees to delay its market entry beyond the point in time when it would have expected to be able to enter the market, for example following a judgment in the litigation, or agrees to enter the market in a more limited fashion than it would have done in the absence of a settlement." It was thus already apparent that it also considered settlements providing for an early generic entry (relative to patent expiry) as potentially suspicious. The wide approach to value transfers was also already evident from the way it categorised settlement agreements.[73] According to the Commission a value transfer would encompass not only direct monetary transfers, but

69 n 2.
70 European Commission, 'Pharmaceutical Sector Inquiry: Final Report' (8 July 2009).
71 ibid, para 22.
72 ibid, para 1351.
73 Although the report claimed that the classification was based solely on the structural features of the agreements, and not on the competitive assessment (Sector Inquiry Final Report (n 3), para 1530).

also distribution agreements, licences and other "side-deals".[74] Furthermore, in the report it was also asserted that companies which are confident of the strength of their patents do not consider settling,[75] a finding which could bear a hint at the US approach to assessing reverse payment settlements based on the perceived weakness of patent claims stemming from the size of the payment.

45. In fact, the sector inquiry report contains a whole section devoted to patent settlements in the USA and its enforcement practice, although it was "deemed not to be transferable to the EU" context because of the regulatory differences.[76] Yet, an overview of the US settlement practice was considered useful to identify common and diverging points between the two systems. Since the report predates the *Actavis* case, it relied on the exposition of earlier contradictory case-law. The point of emphasis, however, was the FTC's eagerness in targeting those agreements.[77] A general comparison of settlement agreements concluded in the EU and the USA revealed a varying number of settlements concluded and a varying content of the agreements with a value transfer – the no-authorised-generic agreements popular in the USA were not found in any settlement concluded in the EU.[78] This could suggest that the problems faced by the competition authorities in the two jurisdictions might not be comparable as settlements concluded in the two jurisdictions differ.

46. In the sector inquiry report the Commission concluded that there was a need for a further monitoring exercise of settlement agreements.[79] In so far as this was a result of a lack of transparency on the issue, in expressing a willingness to supervise settlement agreements, the Commission mirrored the US approach under which all settlement agreements entered into by the pharmaceutical companies need to be filed with the FTC and the DoJ.[80] When referring to the US practice on the point, the report also noted legislative initiatives aiming at making certain settlements with a value transfer

74 ibid, para 742 (box); a majority of settlement agreements with a value transfer (B.II type in the Report classification) included a licence agreement (29 out of 45; para 772).

75 ibid, para 720.

76 ibid, para 780.

77 ibid, para 789.

78 ibid, para 794.

79 These are conducted on the same basis as the Sector Inquiry, investigation is based on the requests for information sent to selected pharmaceutical producers.

80 Sector Inquiry (n 2), para 1531. There exists no analogous obligation under EU law, information for the monitoring reports is gathered using requests for information under art 18 of Regulation 1/2003.

unlawful.[81] Ever since 2010, a monitoring report scrutinising pharmaceutical patent settlements concluded in the EU is issued on an annual basis. The monitoring reports use the same wide definition of a value transfer whereby even non-assert clauses on the part of the originator may be considered a value transfer.[82] Although considering settlement agreements with a value transfer as deserving the highest level of competition scrutiny,[83] the reports state that no presumption of violating competition rules applies to those settlements.[84] Indeed, the reports recognise that some of the settlements with a value transfer might be procompetitive.[85]

47. On the basis of the data collected as part of the monitoring exercise, the Commission claims that the fears that antitrust scrutiny of reverse payment settlements would have a negative effect on the ability to conclude settlements and the corresponding need to litigate cases till the end have proved unfounded. It appears, however, that the data collected by the Commission does not allow for such conclusion. While it is true that the number of settlements concluded in the years following the sector inquiry (which was a first sign that the Commission considers reverse payment settlements suspicious) has increased, even the Commission admitted that this may have been for a variety of reasons.[86] Moreover, the reports do not measure settlements as a proportion of litigated cases, so it remains uncertain whether the Commission's scrutiny had an effect on companies' behaviour in handing disputes. Furthermore, the reports for the years 2013-2014 showed that the number of settlements during those years decreased relative to the peak year of 2012.[87] This might be significant for it might be going against the Commission's suggestions that antitrust scrutiny had no

81 A number of legislative proposals have been put forward in the US to outlaw reverse payment settlements, none of which succeeded so far. However, legislative interest in the matter is reflective of the controversy those settlements cause in the US.

82 European Commission, 5th Report on the Monitoring of Patent Settlements (period: January-December 2013), para 12.

83 ibid, para 17.

84 European Commission, 4th Report on the Monitoring of Patent Settlements (period: January-December 2012), para 13.

85 ibid. Based on the timing of generic entry compared to what the parties expect to be the outcome of the litigation.

86 ibid, para 23, listing reasons such as medicines losing patent protection, general increase in litigation and disputes, greater readiness to settle and new legislation in Portugal. Another reason, unaccounted for in the reports, might be that the Commission's access to information has changed over the years – as there exists no general obligation to report patent settlements in the EU the Commission has to rely on requests for information and the number of companies subject to those requests might have changed over the years (to that effect the reports only state that requests were sent to companies that cooperated in the Sector Inquiry and whose settlement agreements were reported in the specialised press).

87 European Commission, 6th Report on the Monitoring of Patent Settlements (period: January-December 2014), para 22.

effects, since these are the years in which *Lundbeck* and *Servier* prohibition decisions were made, which gave a more precise idea of the nature of the Commission's objection against reverse payment settlements concluded in the pharmaceutical sector.

48. The treatment of reverse payment settlements in the sector inquiry report is consequential because both *Lundbeck* and *Servier* decisions relied on its findings, not only as background information, but also in support of the arguments against those settlements.[88]

Lundbeck and Servier

49. The prohibition decisions reached in *Lundbeck* and *Servier* both concerned settlements made in respect of blockbuster drugs, in the first case an antidepressant citalopram, and perindopril, a ACE inhibitor used for treatment of cardiovascular diseases, in the second case. In both cases the patents on the compound have already expired and the underlying disputes with the generic producers concerned infringement and/or validity of process patents.[89] The *Lundbeck* decision concerned six agreements concluded by Lundbeck with four generic producers: Merck, Arrow, Alpharma and Ranbaxy. Although the details of the agreements varied, they all involved a cash payment from Lundbeck to the generic producers in return for them not entering the market. Similarly, the *Servier* decision concerned a series of agreements with Niche/Unichem, Matrix (now Mylan), Teva, Krka and Lupin. While these also included value transfers, the agreements were more varied. Apart from cash payments, the value transfers also took the form of a distribution agreement with a liquidated damages clause, patent acquisitions (considered also a separate violation of article 102) and a licence which allowed for dividing the market (Krka agreement).

The test for establishing potential anticompetitiveness

50. The Commission considered reverse payment settlements concluded by Lundbeck and Servier to be restrictions of competition by object, and so anticompetitive by their very nature. At the same time, it acknowledged that patent holders are generally free to exclude competitors from using the patented invention and are generally entitled to settle patent litigation. Still, it considered that a transfer of value constitutes an

88 See e.g. *Servier* (n 55), para 1131, where the Commission cites statistics on the percentage of litigation cases won by generic producers in support of the argument that potential competition existed and that patent challenges form the essence of competition in the pharmaceutical sector.

89 Patents protecting the method of producing known substances.

inducement to the generic producer that reduces its incentives "to pursue independent efforts to enter the market" and to substitute the risks of competition for practical cooperation.[90]

51. In effect, it has devised a test, which would allow for identification of agreements that can be potentially anticompetitive, consisting of three elements which need to be analysed taking into account the economic and legal context of the agreements: 1) whether the originator and the generic producer are at least potential competitors, 2) whether the generic producer committed to limit its independent efforts to enter one or more of the EEA markets with its product as part of the agreement, and 3) whether the agreement was related to a value transfer from the originator producer as a significant inducement which substantially reduced the generic producer's incentives to independently pursue its efforts to enter one or more of the EEA markets with its product.[91]

52. The test, thus worded, encompasses agreements that allow for early entry, such as distribution or licensing agreements, since the focus of the test is on independent entry. More importantly, however, the test applies regardless of the question of patent validity. Similarly to its US counterparts, the Commission did not apply the scope of the patent test, and instead considered that reverse payment settlements can be anticompetitive regardless of the question of patent validity. In the words of the Commission: "[t]he means used by the patent holders to defend their rights matter."[92] This approach has been contested by the parties, however the Commission countered that the scope of the patent test is not supported by the case-law of the CJEU and in any case it would be ill-suited. Relying on older case-law[93] it stated that exercise of intellectual property rights may fall within article 101(1). The Commission considered that the scope of the patent test unjustifiably assumes that the generic medicine infringes on the originator's patent, which it regarded a one-sided view which is "unreliable and inconsistent with the substantial uncertainty" existing at the time the

90 *Servier* (n 55), paras 1102 and 1106.

91 ibid, para 1154; *Lundbeck* (n 69), para 661.

92 *Servier* (n 55), para 1137.

93 Case C-78/70 *Deutsche Grammophon v Metro* EU:C:1971:59 and Case C-40/70 *Sirena v Elda* EU:C:1971:18. It also referred to *Grundig*, *Keurkoop v Nancy Kean Gifts* and *RTE* to further affirm that competition rules only protect legitimate exercise of IPR (Joined cases C-56/64 and 58/64 *Grundig v Commission* EU:C:1966:41, Case C-144/81 *Keurkoop v Nancy Kean Gifts* EU:C:1982:289, Case T-69/89 *RTE v Commission* EU:T:1991:39).

agreements in question were concluded.[94] Disregarding the fact that a patent might be valid and infringed though, might be equally one-sided.

53. The Commission's approach to the question of anticompetitiveness based on the inducement provided by the payment differed from that taken by the Court in that respect. Although the General Court also considered reverse payment settlements to be anticompetitive by object, it took the size of the payment as an indication of the weakness of a patent and the fact that the originator was not convinced of its chances of succeeding in litigation[95] to supplement the reasoning based on inducement.[96] To support its argument the Court relied on the *Actavis* case to say that it also considered the size of the payment a workable surrogate for the analysis of patent validity. This bringing of the reasoning of the Court in line with its US counterpart is significant for it exposes an antitrust action to a defence based on patent validity as it might be later confirmed by a patent court.[97] The reasoning based on inducement taken up by the Commission did not suffer from this deficiency. The Court's approach instead potentially brings antitrust findings in conflict with patent law. Since the Commission appeared to have found a way round this problem, as already highlighted in the dissenting opinion in *Actavis*, this conclusion on the part of the Court seemed unnecessary and problematic.

54. While both the Commission and the Court rejected an argument based on the scope of the patent, the Commission expounded on an understanding of the subject-matter of the patent, which it considered to be an expression of the same conceptual approach as the distinction between existence and exercise of rights.[98] Similarly, the Court also relied on the existence/exercise distinction.[99] According to the Commission:

> The concept of the subject-matter is an expression of the reasoning that for each intellectual property right it is possible to identify a number of

94 *Servier* (n 61), para 1196.
95 *Lundbeck* (n 2), Para 353.
96 ibid, para 360.
97 Even though this point has been raised by the applicants in *Lundbeck* (n 2), para 466.
98 ibid, fn 1570. Valentine Korah , *An introductory guide to EC competition law and practice* (Hart Publishing 2004), p 337: "In legal theory, it is impossible to draw the line between existence and exercise, except at the extremes. Analytically, the existence of a right consists of all the ways in which it may be exercised." It is a "distinction which cannot be drawn by logical analysis". See further ch 10 for a discussion of the existence/exercise distinction.
99 *Lundbeck* (n 2), para 118.

> core rights which the owner of that right enjoys under national law and whose exercise is not affected by the Treaty rules.[100]

In defining the subject-matter of the patent the Commission also relied on previous case-law, in particular on *Centrafarm BV and Others v Sterling Drug*,[101] to conclude that although the 'right to oppose' infringements forms part of the subject-matter of the patent right,[102] "paying or otherwise inducing potential competitors to stay out of the market" does not. The relevant question should be, however, whether settling a dispute is part of the right to oppose or otherwise part of the subject-matter of the patent. This point has been raised as an argument in the appeal against the Commission's decision, but it has been ignored by the Court by rejecting the scope of the patent argument.[103] At the same time, the Court backed the Commission's approach by stating that "even if the agreements at issue also contained restrictions potentially falling within the scope of the applicants' patents, those agreements went beyond the specific subject matter of their intellectual property rights, which indeed included the right to oppose infringements, but not the right to conclude agreements by which actual or potential competitors were paid not to enter the market."[104] It also considered that the applicants were wrong to suggest that article 101(1) applies to intellectual property only in exceptional circumstances,[105] suggesting that the approach taken in *Microsoft* in the context of the application of article 102 is not transferable to the anticompetitive agreements context.

55. Although the Commission rejected the scope of the patent test as a limitation on antitrust scrutiny of patent matters, it referred to the scope of the patent to point out that some of the agreements concluded by Lundbeck went beyond what it could have achieved by winning patent litigation, and so went beyond patent scope, thus highlighting the anticompetitiveness of the agreements in question.[106] The problem with the agreements was not that they extended beyond patent duration, but rather that they did not refer to the allegedly infringing processes and instead prohibited any

100 ibid.
101 Case C-15/74 [1974] ECR 1147.
102 *Servier* (n 55), para 1121.
103 *Lundbeck* (n 2), para 503
104 ibid, para 495.
105 ibid, para 499.
106 *Lundbeck* (n 69), paras 605, 1085 and fn 1874.

independent generic entry, even that based on future processes regardless of the question of patent infringement.

56. While the Commission admitted that payment can be a condition *sine qua non* for the conclusion of a settlement,[107] its assessment of the anticompetitiveness of the agreements was unaffected by the possible existence of other legitimate objectives the parties might have pursued.[108] Thus, it did not consider it relevant that the 'inducement' for the generic producer might have been simply a reflection of the dynamics of negotiation in which the parties disagree on the strength of the patent that bridges the parties' expectations about the outcome of litigation. In its view the settlements did not result out of the strength of the patent, but rather from the inducement in form of the value transfer to the generic producer.[109]

No-challenge clauses

57. As part of the *Servier* and *Lundbeck* decisions the Commission attacked no-challenge clauses contained in the settlement agreements. In doing so it relied on the *Windsurfing* judgment in which no-challenge clauses were prohibited by the Court when used in a licence agreement, since they unduly restrained a possibility of competition that could arise out of legal actions and improperly substituted the licensor's "discretion for the decisions of national courts, which were the proper forum for actions".[110] That judgment, however, concerned a different context - the no-challenge clause in *Windsurfing* was used to prevent a patent dispute from arising by means of a contractual clause imposed on the potential challenger rather than as means of resolving an already existing challenge (agreeing to step away from litigation). Indeed, it has been argued by the parties that no-challenge clauses are inherent in the patent settlement context, the very purpose of which is to put an end to a dispute. Similar clauses normally also form part of settlements without value transfers. It would seem that a no-challenge clause that is restricted to the alleged patent infringement or to the question of validity of the patent which was the subject of litigation/dispute between the parties would be the very essence of a settlement that as such should not be objectionable. Indeed, in *Lundbeck*, one of the points of criticisms levelled against the settlements concluded by Lundbeck was that they did

107 *Servier* (n 55), para 1185.
108 See e.g. *Lundbeck* (n 69), paras 802 and 814.
109 ibid, para 870.
110 Case C-193/83 *Windsurfing International v Commission* [1986] ECR 00611, para 52.

not resolve any patent dispute and did not contain any commitment from Lundbeck to refrain from infringement proceedings.[111] Perhaps it was this inequality of obligations put on the parties as part of the settlement that made the no-challenge clauses objectionable.

58. While admitting that similar obligations might be found in other settlements, the Commission considered that these need to be assessed taking into account the actual context of the settlements and the balance of contractual rights and obligations. It considered that the difference between settlements with and without value transfers lay in the fact that only in the latter case any limitations on commercial behaviour are "directly and exclusively" a result of the strength of the patent.[112] In such circumstances a settlement was said to be unlikely to breach competition law. At the same time, the Court considered that the presence of no-challenge clauses was not one of the relevant factors in classifying the agreements as restrictions by object.[113]

59. To support their argument the parties also referred to the Technology Transfer Guidelines which state that no-challenge clauses generally fall outside of article 101(1) in the context of a settlement, since they are inherent in such agreements.[114] The Commission considered, however, that the Guidelines were not applicable to the present circumstances, since they analysed no-challenge clauses on a stand-alone basis and not in combination with other elements, such as value transfers, forming part of the obligation.[115] It thus rejected the parties' arguments that the Guidelines should be applied by analogy.[116]

Managing uncertainty

60. Although the assessment made by the Commission was necessarily performed in the conditions of uncertainty, the Commission contended that it was unnecessary for it to rely on posterior patent court decisions or to perform its own assessment of the patent strength and of the likely outcome of litigation if such continued.[117] This is because it

111 *Lundbeck* (n 69), para 6.
112 *Servier* (n 55), para 1136
113 *Lundbeck* (n 2), para 701.
114 Point 209 of the Commission Guidelines on the application of Article 81 of the EC Treaty to technology transfer agreements [2004] OJ C 101. The 2004 Guidelines have since been replaced by the 2014 Guidelines [2014] OJ C 089.
115 *Servier* (n 55), fn 1586.
116 It is also interesting to note that all attempts by the parties to apply TTBER Guidelines even if only by analogy were rejected by the Commission, while at the same time it has relied on those by analogy where this supported its own arguments (see e.g. *Servier* (n 55), para 1187).
117 *Servier* (n 55), para 1144.

was enough that the inducement in form of payment affected the incentives of the generic producer to continue with the litigation and that was enough to find a restriction of competition, litigation being part of the competitive process in the patent context. In that way the Commission tried to avoid dealing with the uncertainty inherent in the patent context. The Court's pronouncement on the issue might have fallen into that trap. Yet, it would seem that even if relying on inducement reasoning, the Commission decisions could not avoid assessing patent validity and likelihood of infringement in one way or another.

61. Firstly, the first prong of the test established by the Commission for identifying settlements restrictive of competition, i.e. the one concerning the question whether the parties to the agreement were potential competitors, requires assessing the likelihood of the generic producer entering the product market. To assess that, the Commission relied on well-established case-law requiring there to be "real concrete possibilities" for the generic producers to compete with the originators. Yet, it is notable that none of the authorities relied on by the Commission concerned a market the entering of which would entail a level of innovative activity (to go round the existing process patents) or indeed the patent context in which entry could be precluded by infringement proceedings.[118] The only exception is the *AstraZeneca* case (discussed in the next chapter),[119] but the question of potential competition was not openly discussed in that case, so the Commission only drew on the suggestive wording of that case.[120] Yet, an assessment of "real concrete possibilities" in the pharmaceutical patent context can prove to be particularly challenging and inevitably relying to a significant degree on guesswork.

62. In the realm of a knowledge-based industry even the assessment of the technological advancement of a project and its chances of success might be very difficult, if not bordering on speculative. In the *Servier* case some of the generic producers did not even have a marketing authorisation at the point of entering into the settlement, so it was not even certain whether they would be able to overcome technological obstacles

118 The cases relied on by the Commission in *Servier* were: Joined cases T-374/94, T-375/94, T-388/94 and T-388/94 *European Night Services and Others v Commission* [1998] ECR II-03141; case T-461/07 *Visa Europe and Visa International Service v European Commission* [2011] ECR II-01729; case T-114/02 *BaByliss v Commission* [2003] ECR II-01279; Case T-112/07 *Hitachi v Commission* [2011] ECR II-03871; and case T-519/09 *Toshiba v Commission* EU:T:2014:263.

119 Case C-457/10 *AstraZeneca v Commission* ECLI:EU:C:2012:770.

120 *Servier* (n 55), para 1165.

to reach the market.[121] The Commission, however, relied on the internal documents to conclude that this was a likely outcome.[122] Even less so, it was not certain whether the processes devised by the generic producers were not infringing on the patent held by Servier/Lundbeck. While the Commission did not question that there was a genuine dispute on that point,[123] it nonetheless seemingly drew some inferences from the internal documents of the parties and made an assessment based on the parties' perceptions of the likelihood of success.[124] This approach might be considered dubious, especially since patent disputes can be notoriously complex and even the parties' subjective assessment of the likelihood of success might be completely wrong. In fact, the *Servier* decision itself provides a good example of how unpredictable patent proceedings can be – the generic producers involved in the settlements participated in the opposition proceedings[125] before the EPO against one of Servier's patents ('947 patent) and all of them expressed a strong confidence in winning those, as noted by the expansive extracts from their internal correspondence quoted in the decision; yet the EPO's Opposition Division upheld the patent to everyone's surprise.[126]

63. This shows that reliance on the parties' perception of the strength of patents for second-guessing the outcome of patent disputes might be considered questionable. Yet, the way in which the Commission relied on those sources appears to be even more objectionable. Throughout the decisions the Commission underlined and quoted at length statements by the generic producers in which they expressed doubts in the validity of the blocking patents or expressed a belief that they were not infringing, but at the same time it downplayed the opposite statements made by the originator producers as expressions of "subjective belief".[127] In the eyes of the Commission it was enough that there was a genuine doubt on both sides as to whether Servier could successfully enforce its patents to establish that there was a real concrete possibility of the generic producers entering the market and thus constituting potential

121 See in particular Teva (para 1528 ff) and Lupin (para 1874 ff).
122 ibid.
123 *Servier* (n 55), para 1170.
124 ibid, para 1172.
125 A procedure whereby any member of the public may centrally challenge the validity of the patent within nine months of publication under one of the technical grounds specified in art 100 EPC.
126 The patent was eventually held invalid by the board of appeal at the EPO, but that does not change the fact that the parties' perception of likelihood of success might not provide good guidance.
127 See e.g. *Lundbeck* (n 69), para 921.

competitors.[128] Merely challenging patents was equally considered an expression of competition.[129] This appears to be a rather low threshold for establishing that the generic producers in question were potential competitors. Within that framework, it is enough for the dispute not to be sham to establish a realistic prospect of success.

64. The Commission's approach has been unsuccessfully challenged before the General Court. The Court confirmed that the Commission may rely on the perception of the undertakings to assess whether other undertakings are potential competitors, even though it acknowledged that a purely theoretical possibility would not be sufficient.[130] As already noted above, such an approach could work well in respect of traditional industries where a patent's existence does not potentially constitute an objective barrier to entry. Instead, in effect it reaffirmed dubious patent assessments based on parties' perceptions. This is despite the fact that in considering the burden of proof put on the Court it considered that any doubt must operate to the advantage of the undertaking to which infringement decision is addressed.[131] Moreover, it has denied allegations that the contested decision was based on a negative bias against process patents.[132] In that connection, it formed a view that the Commission has shown that Lundbeck's patents were not capable of blocking a generic entry.[133] Basing one's assessment on subjective criteria might, however, be the essence of such bias.

65. Further, the Commission argued that, unlike the presumption of patent validity, there is no presumption of patent infringement. While it is no doubt correct to say that a mere allegation of patent infringement does not mean that there has been an infringement and that this needs to be proven by the patent holder, equally it does not mean that there was no infringement. In the context of a genuine dispute the balance does not lean either way in respect of an individual dispute at stake. In the same vein, both the Commission and the Court appear to be undermining the presumption of patent validity, a principle well established as a matter of patent law. While they clearly acknowledged the existence of that principle,[134] they both relied on the parties' beliefs to suggest that there was a realistic prospect of invalidation of certain

128 *Servier* (n 55), para 1172.
129 *Lundbeck* (n 69), para 625.
130 *Lundbeck* (n 2), para 104. The Commission "did not err in relying on *objective* documents reflecting the perception that the parties to the agreements at issue had of the strength of Lundbeck's process patents" (para 141, emphasis added).
131 ibid, para 106.
132 ibid, para 166.
133 ibid.
134 *Lundbeck* (n 69), para 77; *Lundbeck* (n 2), para 121.

patents.[135] They thus implicitly rejected the parties' arguments that their conviction that a court might declare patents in question invalid should be considered irrelevant in light of the presumption of validity of patents.[136] It was thus concluded that potential competition existed because it was "far from certain" that a judge would have found the patents infringing.[137]

66. Yet another aspect of the *Servier* decision in which the Commission had to build an approach to uncertainty in the patent context was when it considered counterfactual scenarios in analysing the effects of the agreements. Similarly to the elements of the analysis considered above, it used the uncertainty inherent in the situation against the parties to the agreements, rather than to give them the benefit of a doubt. In particular, it used a counterfactual scenario of earlier generic presence on the market to suggest that settlements caused generic delay causing harm to consumers,[138] where in fact this was subject to uncertainty. It was entirely possible that the originators would have prevailed in the patent cases, in which case no generic entry would have occurred or if it did it would have been stopped with the use of an injunction. Yet, the Commission considered that generic producers would have remained potential competitors. In doing so, it again underlined the parties perception of the likelihood of success in a patent action.[139] In respect of Krka, a generic producer who at the time had a completed product which received marketing authorisation, the Commission claimed that it could have challenged Servier's patents or enter the market at risk and thus remain a competitive threat to Servier. Again, this assertion ignored a possibility that Krka could have lost a patent challenge and thus be only a very short term threat. In considering the counterfactuals, the Commission appeared to emphasise one possible alternative over the other, i.e. the one in which a generic entry occurs absent the agreement. At the same time, it was sceptical about the generic producers' incentives to continue their efforts at going round the patents following the settlement, even when the settlement did not prevent such possibility. Although the Commission considered the removal of generic company as a potential competitor a concrete effect of the agreements, it considered itself obliged only to show likely effects of the

135 *Lundbeck* (n 69), paras 628, 669, 833 and 834; *Lundbeck* (n 2), paras 120, 122, 196, 254 and 435.
136 *Lundbeck* (n 69), para 1036.
137 ibid, para 836.
138 *Servier* (n 55), para 1243.
139 ibid, para 1386.

agreements,[140] a fact which it used to its advantage, since it was enough to show that a real possibility existed that the agreements prevented a more pro-competitive outcome.

67. Notwithstanding all of the above, the Commission claimed that it was not necessary for it to assess patents at stake in those cases or to second guess the decisions of the patent courts. At the same time, it asserted that it was competent to make patent assessments under certain conditions.[141] The Commission relied on the *Windsurfing* case for this controversial statement, but did not specify what were the conditions under which patent assessment could be performed by the Commission or how this assessment would look like exactly.[142] It only stated that such assessment would be without prejudice to later findings of the national courts, based on the legal position in the Member States in which the patent was granted, while still subject to review by the European courts for reasonableness.[143] The Commission's assertion of competence appears to rely on the need to be able to exercise its powers as is apparent from the extract from the *Windsurfing* case it quoted in that connection.[144]

68. Overall, throughout the decision the Commission appeared to be highlighting perceived patent weakness to strengthen its case, although it claimed that patent validity was not relevant for the outcome of the assessment. In that sense a certain parallel could also be drawn between the Commission decisions and the approach taken by the US Supreme Court in *Actavis*, which relied on the perception of patent weakness to support identification of certain settlements as suspicious.

Failure of the patent system?

69. One of the arguments put forward by Servier in an attempt to refute the Commission's analysis was that it was operating on an assumption of market failure "deriving from the patent grant system, which the Commission seeks to regulate by competition law intervention".[145] The Commission, however, rejected the claim that adjudicating patent issues is a 'weak' part of the patent process in the EU, despite acknowledging that the patent system has some shortcomings.[146] In any case, it did not consider that Servier

140 ibid, para 1219.
141 ibid, para 1204; the Commission's competence to make such patent assessments in the context of antitrust infringement was confirmed by the General Court in *Lundbeck* (n 2), para 119.
142 Case C-193/83 *Windsurfing International v Commission* [1986] ECR 00611.
143 *Servier* (n 55), fn 1705.
144 ibid.
145 ibid, para 1204.
146 ibid, referring to the Sector Inquiry.

has shown that the claimed deficiencies could justify the use of settlements with reverse payments.

70. In the same vein, the Commission dismissed Servier's claim that its behaviour was justified by the asymmetry of risks resulting from a difficulty of obtaining injunctions. The Commission did not feel that Servier sufficiently substantiated its claim of inability of obtaining injunctions. In any case, the question of availability of injunctions was considered a matter that should properly be left to the judicial assessment in a patent case.[147] Equally, a loss of exclusivity resulting from a refusal of an injunction was seen as a risk inherent in competition.[148] This risk was not, however, entertained by Servier in the case at hand, since none of the generic producers involved in the settlements entered the market at risk, an event which would trigger the need for an injunctive remedy. On a more general level, the Commission considered that asymmetry of risks between the parties was built-in in any situation in which loss of patent exclusivity was at stake, and thus was not something caused by the difficulty of obtaining an injunction, even accepting that this was indeed a problem. Furthermore, the Commission considered that Servier could still claim damages, even if an injunction was not available.[149] Equally, for the General Court in *Lundbeck*, the asymmetry of risk was not a sufficient explanation for concluding a reverse payment settlement.[150] That view, however, did not take into account that damages are not always a sufficient remedy, since loss of exclusivity can have irreversible effects on prices in the regulated pharmaceutical industry with national reimbursement systems. According to the Court, such possibility was a normal commercial risk which cannot justify conclusion of anticompetitive agreements.[151]

71. In effect, the Commission rejected a view that imperfections of the patent enforcement system could affect its assessment of the settlement agreements at hand. Whether this was a result of the claim simply not being made out on the facts, or a more principled stand is not entirely clear. It has been argued, however, that assessment of reverse payment settlements should be made against the background of patent system imperfections.[152] According to Subiotto, limited availability of preliminary

147 cf SEP cases discussed in ch 6.
148 *Servier* (n 55), para 1149.
149 ibid.
150 *Lundbeck* (n 2), para 263, 370 ff.
151 ibid, para 385.
152 Romano Subiotto, "The Implications of the Imperfect European Patent Enforcement System on the Assessment of Reverse Payment Settlements" (2014) OECD Expert Paper, DAF/COMP/WD(2014)75.

injunctions, insufficient compensation and lack of unified patent judiciary could all be used to explain the attractiveness of reverse payment settlements to the originators. All of these defects of the patent system can create losses that an originator can sustain even in the event of the litigation being successful, making settlements attractive regardless of the strength of the patent. Subiotto describes it as a form of 'hold up' exerted by the generic producers in which the "difference between the originator's actual losses and the lower compensation it will obtain in litigation constitutes a seemingly 'invisible' value transfer from the originator to the infringing generic company."[153] In this scenario the originator is trying to avoid the "invisible" value transfer by offering a "visible" value transfer in form of a reverse payment settlement.[154] While this portrayal of the issue surely could not explain all reverse payment settlements, it is significant for it shows that certain defects of the patent system might affect the originators' incentives beyond the question of patent strength. This puts into question the Commission's approach whereby settlements can be legitimately concluded only on the basis of the patent strength to avoid antitrust liability.

72. While Subiotto does not identify exactly what significance patent system imperfections should have for the competitive assessment, his observations suggest that there is a lot to be said about solving at least part of the reverse payment settlement problem through improvements to patent law. They also highlight the need to pay attention to the dynamics of the patent system, not just its deficiencies, in assessing patent settlements. As the sector inquiry has shown, inherent uncertainty involved in patent litigation plays an important role for both the originators and generic producers as a factor in deciding whether to enter into a patent settlement. Indeed, for the generic producers this consideration turned out to be just as important as the strength of the case.[155] That inherent uncertainty must be seen amplified by the fact that there exists no unified patent judiciary in the EU.

73. Inversely, could it be said that antitrust intervention was based on the perceived need to correct the imperfections of the patent system that might be unjustifiably deterring generic entry through uncertainty it creates? Was the Commission really solving a problem of market failure deriving from the patent grant system as suggested at the

153 ibid, para 10.
154 ibid.
155 Sector Inquiry Final Report (n 3), paras 735-739.

outset of this section? The uncertainty of the patent system stems not only from the risks inherent in litigation, but is also magnified by the nature of patent granting process itself. The patent granting procedure, even if supplanted by examination of the application at the patent office, fails to weed out all undeserving applications. So much so that we can speak of only 'probabilistic patents' before they are tested in courts.[156] As pointed out in the Pharmaceutical Sector Inquiry Report, following a challenge to validity patents were revoked in the majority of litigated cases in which a final judgment was given.[157] Weak patents, though theoretically harmless, since they should fail at the point in which the right holder attempts to enforce them,[158] can still have harmful effects by becoming a deterrent on the generic producers uncertain of their validity.[159] The examination procedure, practiced at the EPO and in the majority of the Member States,[160] serves to reduce that deterrent effect.

74. While this increases certainty over the question of patent validity and serves a public interest of excluding applications that do not warrant protection, patent offices might still display a level of 'rational ignorance'.[161] With the number of patent applications and filings[162] continuously on the rise,[163] the EPO would require a lot more resources to examine more scrupulously all the applications it receives. This could be considered wasteful considering the fact that the majority of patent rights have little or no commercial significance.[164] Litigation might thus be seen as a more targeted means of

156 Mark A Lemley and Carl Shapiro, "Probabilistic Patents" (2005) 19 Journal of Economic Perspectives 75.

157 Pharmaceutical Sector Inquiry Report (n 3), para 622; patents were revoked in 55 per cent of cases under consideration. This figure does not take into account cases in which parties stepped away from litigation or otherwise a final judgment has not been rendered. Also, patent validity was an issue in 52 per cent of cases in which a final judgment was given (78 out of 149), para 619 ff.

158 Patent applicants might still have strategic reasons to make patent applications in respect of weak inventions that they might suspect not to deserve a grant of a right. Among those are: the use of patents to obtain financing and boost market valuation, use of patents as signalling mechanisms or as part of a larger patent portfolio (Lemley and Shapiro (n 156), p 81).

159 See Mark A Lemley, "Rational Ignorance at the Patent Office" (2001) 95(4) Northwestern University Law Review, pp 20-21 for an argument against overstating the strength this deterrence effect.

160 With some exceptions: Jan Brinkhof and Ansgar Ohly, "Towards a Unified Patent Court in Europe", in Ansgar Ohly and Justine Pila (eds) *The Europeanization of Intellectual Property Law: Towards a European Legal Methodology* (OUP 2013), p 203. Lionel Bently and Brad Sherman, *Intellectual Property Law* (OUP 2014, 4th edn), p 422 point to a falling number of applications in those Member States as a possible reason for dispensing with examination.

161 Lemley (n 159).

162 Patent filing is a preliminary patent application activity indicating the potential interest of innovating businesses from all over the world in the European technology market.

163 In 2015 alone the EPO received 278 867 filings and 160 022 applications, see the EPOs annual reports, available at http://www.epo.org/about-us/annual-reports-statistics/annual-report.html (accessed 21 February 2017).

164 Lemley (n 159), p 2, based on the analysis of the US market, but trends should be similar in the EU.

assessing patent validity.[165] This is not to say that there can be no ways of improving effectiveness of the examination procedure without incurring significant expenses. One way of this conundrum could be to reform the patent system to resemble that adapted in Japan. There, patent applications are subject only to a registration, but need to be examined before the patent holder decides to enforce them.[166] This approach, however, does not remove (rather it amplifies) the uncertainty that might be entertained by the generic producers prior to enforcement (assuming their knowledge of the registered inventions).

75. The system, thus, to a large extent relies on private enforcement. The incentive to challenge patents on the part of the generic producers might, however, be curtailed by the phenomenon of free-riding (i.e. the fact that all generic producers can benefit from an individual challenge at the expense of the generic producer who brought it) and the fact that it might be easier to agree to license than to continue with expensive and time-consuming litigation.[167] Reliance of the patent system on private enforcement makes the opposition proceedings before the EPO an important element of the system by ensuring European wide-effects of patent annulment. Even with forthcoming Europanisation of the patent litigation system[168] a system that is reliant on litigation can be burdensome for both originators and generic producers because of the risks inherent in litigation. This works towards explaining a willingness to conclude settlements. Yet, in those circumstances, a reduction of the number of challenges occurring through conclusion of patent settlements becomes a significant problem since it might mean that undeserving patents might be left unchecked.

76. An acceptance of the probabilistic nature of the patent system could however, also lead to a call for the weakening of the presumption of patent validity, already indirectly called into question by the Commission and the Court in *Lundbeck* and *Servier*. Seeing how many patents are annulled post-grant might suggest that the 'right to oppose' is really just a right to *try* to oppose.[169] The Commission's and the Court's approach to reverse patent settlements suggests that this is the way they understand the functioning of the patent system. Yet, the apparent putting into question of patent

165 Pharmaceutical Sector Inquiry (n 3) notes that top six INNs were the object of nearly half (49%) of all reported litigations (para 602) and that the vast majority (83%) of all reported cases concerned best-selling INNs (T50) (para 606).

166 Lemley (n 159), p 30.

167 Lemley, (n 159), p 19.

168 See further ch 10.

169 Carl Shapiro, "Antitrust Limits to Patent Settlements" (2003) 34(2) RAND Journal of Economics 391 as cited in Lemley and Shapiro (n 156), p 75.

quality as implied in *Lundbeck* and *Servier* decisions not only pertains to the question of patent validity, but also to patentability criteria, which might be interpreted too widely with the effect being that patent rights are granted over trivial inventions thus unduly expanding exclusivity enjoyed by pharmaceutical producers over medicinal products. The Commission's remarks on process patents could be considered a call for (i.e. *signalling*) a re-interpretation of the understanding the criteria of patentability. After all, an inefficient patent system based on low quality patents can be hardly said to be a good stimulant of innovation.[170]

Long term effects

77. The ramifications for the patent system that antitrust involvement in the issue of reverse payment settlements might have point to the need to consider long term effects of finding such agreements anticompetitive. In fact, the parties raised an argument against the legal test proposed by the Commission to the effect that its analysis does not take sufficient account of the long term effects on the incentives to innovate of prohibiting settlements with a value transfer.[171] By referring to the arguments made in reply to the SO (statement of objections) the Commission chose to directly address the issue, which without doubts was a positive development, since this issue should be at the heart of devising a test that well differentiates legitimate settlements from the truly anticompetitive ones. Yet, the Commission readily dismissed the parties' allegations. In doing so, it made several rebutting arguments in an attempt to show that the decision would not necessarily stifle dynamic competition. First, it recalled that not all settlements with a value transfer would be considered restrictive of competition. It is hard to imagine, however, which of the third type of settlements (i.e. those not allowing for an immediate entry, as discussed at the outset of this chapter) would not be caught by the Commission's test, since all value transfers could be taken to be an inducement for the generic producer to enter into an agreement, even if taking a form of a licence.[172] Admittedly, the test is qualified to *significant* inducements that *substantially* reduce the generics' incentives to enter the market, but since those

170 Lemley and Shapiro (n 156), p 77.

171 *Servier* (n 55), para 1206.

172 See para 8 above for the types of settlements. It would seem that the only type of a settlement in which a payment is transferred from the originator to the generic producer that would be found acceptable within this framework is one in which the originator accepts that there was no-infringement/patent is invalid, accepts immediate independent generic entry and offers to pay damages for the period of delay (type 2). This obviously excludes agreements where the parties have not agreed on who is at fault.

qualifiers are not readily assessable, the result might be that the originators will feel compelled to abstain from any settlements with a value transfer to avoid antitrust liability. If this is taken to include agreements that allow for some form of generic entry prior to patent expiry even if not immediate, for example through a licensing agreement, then the outcome might be problematic.

78. Second, the Commission considered that averting the possibility of an earlier generic entry bestows on the patent holder protection beyond that provided by the patent system.[173] This argument is based on the reasoning that the patent system does not shield from patent challenges. Equally though, the patent system does not preclude patent settlements. The point made in respect of long term effects of the prohibition of reverse payment settlements in so wide terms is precisely that the originators will have to engage in continued litigation without a possibility of a settlement in a greater number of cases, thus reducing the value of the patent.

79. To support that argument further, the Commission relied on the passage from *AstraZeneca* explaining that a "misuse of the patent system potentially reduces the incentive to engage in innovation, since it enables the company in a dominant position to maintain its exclusivity beyond the period envisaged by the legislator."[174] In the context of reverse payment settlements, in which the question of patent validity and infringement remains uncertain, it is not known, however, whether the originator can maintain its exclusivity beyond the period envisaged by the legislator. If the patent was to be found valid and infringed, generic entry exclusion would fall within the scope of patent exclusivity as envisaged by the legislator (subject to a possibility that the settlement extended beyond what the patent holder could have achieved if litigation continued) suggesting that the reasoning from *AstraZeneca* can be hardly applicable to these circumstances.

80. Relying on the logic of misuse as expressed in *AstraZeneca*, the Commission continued to state that undue delay of generic entry reduces the originator's incentives to innovate by removing the competitive pressure and that extending the innovator's profits does not necessarily lead to increased levels of innovative activity. Again, in the circumstances of uncertainty relating to the question of patent validity/infringement it is not clear whether delay in generic entry is in fact undue or

173 *Servier* (n 55), para 1206.

174 ibid, citing para 367 of the judgment of the General Court: Case T-321/05 *AstraZeneca v Commission* [2010] ECR II-02805; see ch 4 for a detailed discussion of the case.

indeed that the innovator's profits are extended. To the contrary, they might be curtailed by the need to continue to engage in litigation without a possibility of an exit in the form of a settlement.[175]

81. In contrast with the above arguments, the last argument used by the Commission appears much stronger: it asserted that the arguments put forward by Servier implied that the overall effect on the originator's expected profits and thus on the incentives to innovate in the long-term is ambiguous.[176] While the costs of dealing with generic challenges could go up, Servier maintained that prohibition of value transfers would reduce the generic producers' incentives to bring patent challenges. The Commission considered that a prohibition of reverse payment settlements would indeed remove the incentive from the generic producers to 'harass' the originators with strategic claims, thus eliminating 'hold-up' strategies. Similarly, in *Lundbeck* it pointed out that elimination of value transfers would reduce the originators exposure to "generic risk" and that this would counterbalance possible increased costs associated with limits on patent settlements.[177]

82. Be it as it may, it still appears that in other parts of the *Servier* decision the Commission equated the notion of consumer harm with consumer interest in price competition. In analysing the economic context it considered reverse payment settlements to be collusion at the expense of the consumers whose interest lies in the lower, off-patent prices.[178] That section remained silent, however, on the interest of consumers in having access to new innovative medication and on the need to protect the incentives to innovate. A similar analysis, also concentrating on short term effects, can be found in the *Lundbeck* decision.[179]

Industry sensitivity

83. Although both Commission decisions contain separate sections devoted to explaining the way the pharmaceutical regulatory framework operates, the significance of the regulatory framework is hardly visible in the competitive analysis that followed, other than as a necessary background information. It was already explained above that the Commission did not consider the alleged defects of the patent system forming part of

175 The General Court concluded in *Lundbeck* (n 2) that the applicants were wrong in their assertion that the contested Commission decision removed all incentive to conclude patent settlements (para 412).
176 *Servier* (n 55), para 1206; *Lundbeck* (n 61), para 711.
177 ibid.
178 *Servier* (n 55), paras 1149-1152.
179 *Lundbeck* (n 69), paras 645-646.

the regulatory background in the pharmaceutical sector to be influential on the assessment of anticompetitiveness of the agreements. One of the rare circumstances in which it took account of the regulatory framework was in respect of the assessment of potential competition and launch at risk.[180] The Commission pointed out that marketing authorisations are not dependent on patent status in order to assert that generic producers have alternative ways to enter the market, including an entry at risk, which should not be confounded with patent infringement.[181] This finding was used to further support the Commission's argument that the parties were potential competitors. At the same time, as already noted above, on the question of damages for infringing entry, it did not take into account the particularities of the pharmaceutical industry that cause decreases in prices to be irreversible, even though that fact was brought to the Commission's attention.[182]

A procompetitive defence?

84. While the Commission claimed in *Servier* that the decision should not be taken to suggest that the Commission considers that all reverse payment settlements should be "condemned",[183] the width of the test it established for a settlement to fall within article 101(1) together with the difficulty of proving an article 101(3) defence indicates otherwise. The difficulty of proving an article 101(3) defence is not confined to the problem of reverse payment settlements and indeed the Commission relied on the elements of the defence that need to be proven as presented in its Guidelines.[184] Any patent settlement agreement though, even one without a value transfer, would have difficulty satisfying the four cumulative criteria established by article 101(3) (creation of efficiency, fair share for the consumers out of the resulting benefits, indispensability of the restrictions, and no elimination of competition), making the fact that the test for identifying competition restrictions under article 101(1) is very all-encompassing even more significant.

85. Any argument claiming efficiency based on innovation would surely fail under this framework because it would not be possible to calculate or estimate the magnitude of the claimed efficiency, not to mention specify how and when the said efficiency would

180 *Lundbeck* (n 69), paras 615-620.
181 *Servier* (n 55), paras 1175-1176.
182 *Lundbeck* (n 69), para 703, *Servier* (n 55), para 2768.
183 *Servier* (n 55), para 2119.
184 Communication from the Commission – Notice: Guidelines on the application of Article 81(3) of the Treaty [2004] OJ C 101/97.

be achieved.[185] In *Servier* and *Lundbeck* all of the efficiency claims failed for lack of substantiation. The efficiency claims concerned, *inter alia*, avoided litigation costs, improved distribution, earlier generic entry, continued commercial existence, process improvement, and securing the incentives to challenge patents and favour generic entry.[186]

86. The rejection of the process improvement defence, although perhaps justified on the facts, still revealed a certain lack of sensitivity to the way technological progress occurs. Servier's acquisition of process patents applications was claimed to be aimed at advancing technical progress and reducing cost. This claim was refused in part because Servier failed to show any use of the process and was unable to produce any documents demonstrating that the teachings of the patent applications acquired have led to the claimed savings. These requirements could be taken to ignore the fact that the technological progress is based on trial and error and that failure is part and parcel of R&D. In this sense an acquisition of a patent application could be taken as an attempt to secure space for development (or preserve freedom to operate, using the Commission's language)[187] in which the likelihood of success is uncertain. However, lack of proper feasibility studies suggested that Servier was not interested in managing those risks, meaning that on the facts it was not interested in using the patent application for continued R&D. And yet, another ground on which the defence was rejected was based on the fact that a transfer of technology on an exclusive basis was not necessary, thus denying the patent holder the ability to control its invention.[188]

87. Efficiency flowing from earlier entry was similarly rejected on the facts in both *Servier* and *Lundbeck* on the basis of the particularities of the agreements which actually prevented earlier entry,[189] so it remains to be seen how the Commission will approach this issue in future cases. Entry in the form of a distribution agreement was addressed by stating that such an agreement could have been concluded separately without restricting competition between the parties[190] – a supposition based on an unlikely counterfactual. As far as the licences given to Krka went, they were equally rejected as an efficiency defence. Krka tried to rely on TTBER and its Guidelines

185 Both of these elements need to be shown to claim an efficiency defence: *Servier* (n 55), para 2066; *Lundbeck* (n 69), para 1215.
186 *Lundbeck* (n 69), para 1217; *Servier* (n 55), para 2069.
187 Sector Inquiry Final Report (n 3), para 1097 ff.
188 *Servier* (n 55), para 2082.
189 *Lundbeck* (n 69), para 1228 ff; *Servier* (n 55), para 2091 ff.
190 *Servier* (n 55), para 2072.

which state that in the context of settlement agreements licensing "is not as such restrictive of competition since it allows the parties to exploit their technologies post agreement".[191] The Commission, however, held that TTBER did not apply because its conditions were not met[192] and that the Guidelines could not be applied to a situation in 18/20 Member States not covered by the licence.[193] The Commission considered that any efficiencies achieved in the seven countries covered by the licence could not be offset against anticompetitive effects in the remaining Member States, thus adapting an all or nothing approach, despite patents being granted on a national basis. In any event, since the Commission considered Krka to be a potential competitor in the seven markets covered by the licence prior to the conclusion of the settlement agreement, it thought that Krka failed to show causation, i.e the reason why its presence in those markets should be attributed to the licence.[194] It thus used the uncertainty surrounding patent infringement against Krka in a situation where the burden of proof was on the latter. This reasoning could be applied to any early entry agreement, since it is impossible to show that absent the settlement entry would have occurred later without knowing the outcome of litigation. If this were the case, it would be a worrisome outcome.

88. Another failed defence which is interesting in the present context was one raised by Teva that reverse payment settlements secure incentives to challenge patents and favour generic entry. In Teva's view, a prohibition would reduce generics' ability to resolve patent litigation, thus increasing costs and risks associated with challenges and bringing generic drugs to the market.[195] This was said to be particularly important, since, unlike in the US, in the EU the regulatory framework does not provide for additional incentives to the generic producers in the form of a period of exclusivity.[196] The only reply to that claim was that while an interest of the generic producers in having patent issues settled quickly was understandable, "patent issues cannot be settled at any price and patent rights are not immune from the application of competition law."[197]

191 n 115, para 204.
192 *Servier* (n 55), para 2098.
193 The decision refers to 18/20 Member States because of the new States acceding in the meantime.
194 *Servier* (n 55), para 2104.
195 *Servier* (n 55), para 2112.
196 See the discussion above on the operation of the Hatch-Waxman Act.
197 *Servier* (n 55), para 2119.

89. Hence, it would appear that the prospects of any efficiency defence to a reverse payment settlement ever succeeding are slim. Under EU law, even an avoidance of litigation costs would fail as a defence despite that fact that even the starkest academic proponents of treating reverse payment settlements as unlawful, like Hovenkamp, think that these should be presumed anticompetitive only if payments are above litigation costs.[198] In the decisions handed down by the Commission, avoidance of litigation costs was rejected as a possible defence as a private cost-saving measure not producing any pro-competitive effects (rather than as not outweighing the restriction) leaving no scope for this defence to succeed in the future.[199]

Application of article 102 to reverse payment settlements

90. As already mentioned at the outset of this section, in *Servier* the Commission also applied article 102 to reverse payment settlements. Together with patent acquisitions it considered it a joint abuse of dominance that went beyond the mere defence of Servier's IPRs.[200] The standard applied to assessing the abuse was that of competition on the merits.[201] The Commission expanded a bit on the meaning of this standard and explained that it encompassed competition on product quality (which can actually be very limited in the pharmaceutical sector when it comes to competition between originators and generic producers), strength of the patented technologies and similar.[202] The Commission's theory of harm was based on the foreclosure effects stemming from Servier's exclusionary strategy.[203] According to the Commission, the conclusion of five settlement agreements and an Azad patent acquisition together formed a "chain of agreements" that "was likely to have a cumulative and self-reinforcing effect"[204] and composed "a clear pattern".[205] Thus, the agreements formed a single and continuous exclusionary strategy.

91. It is not entirely clear, however, how this strategy amounted to an unlawful strategy other than through use of agreements that were individually anticompetitive. While without doubts the agreements were more interesting to Servier collectively, every

198 Herbert Hovenkamp Mark Janis, Mark A Lemley, "Anticompetitive Settlement of Intellectual Property Disputes'" (2003) 87 Min. L. Rev. 1719.
199 *Lundbeck* (n 69), para 1223.
200 *Servier* (n 69), paras 2764 and 2773.
201 ibid, para 2763.
202 ibid, para 2766.
203 ibid.
204 ibid, para 2933.
205 ibid, para 2936.

patent defence strategy makes commercial sense only if applied cumulatively against all challenges, rather than only selected ones, for it makes sense only for as long as market exclusivity is preserved. Obviously, it formed a pattern, but only in so far as challenges came in within a relatively short period of time from each other and similar means were used to exclude the generic producers from the market. Hence, it would seem that it is hard to identify an additional element that made Servier's strategy unlawful other than as a sum of individually unlawful agreements that together added up to the foreclosure effects.

92. The assessment of Servier's strategy in so far as it consisted of patent acquisitions and reverse payment settlements was without prejudice to other elements of the strategy to delay generic entry identified by the Commission in the decision, in particular the use of patent clusters ("paper patents")[206] and raising regulatory standards.[207] Indeed, the Commission confirmed that those practices were not in themselves problematic from the competition law perspective.[208] Interestingly, the Commission also stated that strategic use of the IPRS and the patent system is also not as such anticompetitive and falls within the definition of the competition on the merits[209] – a statement which could be contrasted with the approach to patent use in *AstraZeneca*, discussed in the next chapter.

VII Conclusions

93. The above discussion revealed that antitrust treatment of reverse payment settlements raises difficult questions about the interaction between antitrust and patent law that might be relevant also from the innovation perspective. It showed that in the conditions of uncertainty surrounding untested patents the tools employed by the competition authorities might be unsuitable to assess the true nature of those agreements. Although the General Court and the US Supreme Court take a somehow

206 ibid, para 115.

207 By publishing monographs in the European Pharmacopoeia, a single reference work for quality control of medicines in Europe used as a scientific and legal basis for quality control compliance with which is necessary for obtaining a marketing authorisation (ibid, para 130 ff). The initial section of the decision describing the elements forming part of Servier's strategy also refers to selective switching to the arginine salt (a newer version of perindopril covered by patent protection, para 110), engagement in patent disputes (paras 110 and 157 ff), sending of warning letters and requests for interim injunctions (para 153 ff), but these strategies are not expressly mentioned in the section assessing Servier's strategy under article 102.

208 ibid, 2764.

209 ibid, para 2766.

differing approach to reverse payment settlements, with the former taking a more decisive stance by considering them restrictions by object, both base their assessments on some rather dubious patent assessments. It remains to be seen though whether the General Court's approach reaffirming the Commissions position will withstand appeal and whether the same reasoning based on presuming patent weakness from the size of the payment will also be used in the *Servier* appeal.[210] It might be that the Court will follow the footsteps of the US Supreme Court in not considering reverse payment settlements to be presumptively restrictive of competition.

94. As things stand now, the Commission established a very interventionist standard of review based on a clear objection to value transfers to the generic producers in all forms in the settlement context - an approach which was reaffirmed by the General Court. In assessing reverse payment settlements the Commission applied a standard of scrutiny that allowed it to go deep into the patent issues. In respect of article 101 intervention it relied on the subject-matter of the patent test said to be identical with the old existence/exercise distinction which for many years appeared to be discredited. For the intervention under article 102, in turn, it referred to the concept of the competition on the merits. At the same time, it claimed that this standard of review did not require it to go into questions of patent validity, which nonetheless it considered to be competent to go into. Yet, the analysis of the decisions has shown that reference to patent validity could not be altogether avoided and that the Commission heavily relied on the parties' perception of the strength of the patents in its assessment, thus revealing the limits of what it can achieve as a competition body. Furthermore, it used the uncertainty surrounding patent disputes to its advantage to establish potential competition and to highlight possible counterfactuals which suited antitrust findings. Although this would seem to go against the presumption of patent validity, a concept central to the patent system, it argued that there is no equivalent presumption of infringement. Moreover, the test devised by the Commission is very wide-encompassing and might also affect settlements in which generic entry is foreseen but not immediately or not on unlimited terms. In this way antitrust involvement might end up being overly inclusive, creating false positives that might act to the detriment of the innovative process. Yet, the Commission seemed undeterred in its course of

[210] Case T-679/14 Action brought on 19 September 2014 – *Teva UK a.o. v Commission.*

action and rejected objections based on the detriment to the innovative competition process and the innovation incentives caused by the test being so all encompassing.

95. On the positive side, it should be noted that the Commission was prepared to address the arguments based on the deficiencies of the patent system as an explanation for the reverse payment settlements or effects on the incentive framework inbuilt into the patent system. However, it readily dismissed them without giving those issues a deeper thought. Overall, it could be said that it showed little sensitivity to the arguments based on the intricacies of the patent system in so far as they served as a defence against finding of antitrust liability. At times, the Commission's approach could be said to be displaying signs of bias against patent holders and the value of their inventions, which could be illustrated by the way in which it approached process patents. Still, antitrust reaction could be described as a reaction to the flaws of the patent system, the elements of which were impliedly criticised in the decisions. Yet, the ability of the patent system to counter the issues pertaining to patent quality might not be such as to completely eliminate uncertainty. Absent a total overhaul of the patent system, patents will remain probabilistic rights, making it possible that in some circumstances patent holders will obtain a benefit where one is not due. In those circumstances finding ways to encourage patent challenges might need to be looked for.

96. On the whole, it could not be said that the decisions made by the Commission were innovation-centred. The Commission was more preoccupied with the potential short term effects of the practices, at the expense of long term effects which were largely side-stepped. Although prepared to go deep into patent issues, the impact of its approach on the functioning of the patent system was not adequately considered, at least not as part of the decisions' reasoning. Consideration of long term effects should, however, be central to a case concerning the most R&D intensive industry and relating to the interaction between antitrust and patent rights. The fact that the regulatory choice to go into patent matters was not matched by an increased sensitivity to patent policy issues made the approach problematic from the innovation perspective.

Chapter 4

Abuse of the patent system - *AstraZeneca* and its aftermath

I Introduction

1. The *AstraZeneca* decision is another antitrust decision concerning the pharmaceutical industry that might be illustrative of problems similar to those faced in the reverse payment settlement context in respect of the treatment of the innovation dimension. Moreover, it is even more clearly grounded in the perception of the insufficiency of the patent law solutions to the problem - a consideration which is expressly relied on by the competition authorities. The Commission decision in *AstraZeneca* can be seen as groundbreaking, since it was its first article 102 determination concerning the pharmaceutical industry,[1] but also, more importantly, because it laid ground for the future antitrust treatment of misuse of the patent system. The aim of this chapter is to deconstruct the policy drivers behind *AstraZeneca* at all stages from the initial Commission decision to the final judgment in that case[2] and to assess the approach to the innovation angle in the context of building of an approach to antitrust-patent interaction developed there.
2. As the analysis below will reveal, the judgment firmly establishes that abuses of the patent procedures are within the realm of antitrust inquiry, but it gives little useful guidance on what constitutes an abuse in this context. The parameters of competition authority's involvement, as delineated by the Court, without doubt constitute a regulatory problem the answer to which will have an impact on the innovation dimension. A greater involvement in patent issues will inevitably have to be more demanding on the Commission in terms of its own reasoning process, if the innovation policy is not to be compromised. Bearing in mind that there are limits as to what the Commission and the Court can achieve as competition bodies, the analysis of the *AstraZeneca* case suggests that they are not entirely successful in that respect and that

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1 The Court of Justice pronouncement in *Syfait* (Case C-53/03 *Synetairismos Farmakopoion Aitolias & Akarnanias (Syfait) and Others v GlaxoSmithKline plc and GlaxoSmithKline AEVE* [2005] ECR I-04609) predates the Commission's decision by two weeks, but that was a preliminary ruling decision.

2 Commission Decision C (2005) 1757 final of 15 June 2005 relating to a proceeding under Article 82 of the EC Treaty and Article 54 of the EEA Agreement (Case COMP/A. 37.507/F3 AstraZeneca); Case T-321/05 *AstraZeneca v Commission* [2010] ECR II-2805; Case C-457/10 P *Astra Zeneca AB and AstraZeneca plc v European Commission* ECLI:EU:C:2012:770.

a proper balancing exercise of the sometimes contrasting policy interests at stake is lacking to the detriment of innovation. The analysis performed shows that incentivising innovation was not key to the case, but rather short-term considerations. Furthermore, the apparent over-inclusiveness of the approach, which might have a chilling effect on innovation, also bears similarity to the reverse payment settlements cases. To this end, the *AstraZeneca* case and its aftermath serve as a useful illustration of the problem.

3. While antitrust involvement in *AstraZeneca* was in part justified by the insufficiency of patent system solutions to the problem of patent abuse, the ways in which patent abuse can be dealt with outside antitrust enforcement are also looked at in the chapter. The analysis suggests that antitrust reaction might indeed be a reaction to a failure of the patent system to counter abuse on its own. The "repair-it-all" position of antitrust law as against the patent system is a characteristic feature of the decision, which should be recalled also for the chapters that will follow.

4. The long lasting dispute about AstraZeneca's abuse of the patent system commenced even before the Commission Sector Inquiry into the Pharmaceutical Sector has been initiated, [3] and indeed it has been suggested that it might have been a driving force that led to that Report.[4] As such, the Sector Inquiry forms an important background to the case at hand and offers a further insight into the Commission's approach into the question of patent abuse. Thus, it will also be considered in this chapter.

5. The chapter below is divided into several sections for ease of analysis. The section immediately following this introduction shortly explains the issue that was faced in the *AstraZeneca* case. Section III takes a deeper look at the nature of the problem confronted in that case and asks whether and in what way it concerns the interaction between competition law and the patent system. Section IV goes on to explore directly what is at the heart of this chapter, which is the innovation angle. In that section, a comparison with the US approach is also made. Section V takes a wider look at the issue and asks about the principal implications of *AstraZeneca* for future cases and an approach that might be applied to other forms of patent misuse. Finally, section VI

[3] European Commission, Pharmaceutical Sector Inquiry: Final Report (8 July 2009); European Commission Press Release IP/08/49 of 16 January 2008: "Antitrust: Commission launches sector inquiry into pharmaceuticals with unannounced inspections".

[4] Mario Siragusa, "EU Pharmaceutical Sector Inquiry. New Forms of Abuse and Article 102" in Giandonato Caggiano, Gabriela Muscolo & Marina Tavassi (eds*), Competition Law and Intellectual Property: A European Perspective* (Kluwer Law International 2012), p 187.

considers alternative ways through which patent abuse can be challenged in an attempt to answer the question whether antitrust involvement is needed.

II The problem faced in *AstraZeneca*

Background

6. AstraZeneca is a pharmaceutical group involved in inventing, developing and producing innovative drugs. Its R&D efforts were rewarded with the invention of a blockbuster drug Losec, used for treatment of gastrointestinal conditions, that became the best-selling drug ever, accounting to almost 40 per cent of AstraZeneca's total sales.[5] As a proprietary medicinal product, Losec was subject to a marketing authorisation under Directive 65/65/EEC.[6] In addition, the now replaced Regulation 1768/92 established that medicinal products subject to a European or a national patent were also entitled to a supplementary protection certificate (SPC), extending the time of patent protection.[7]

7. The purpose of SPCs is to reflect on the reduction of effective patent protection caused by the additional requirement to obtain a marketing authorisation for medicinal products before they can be placed on the market. The effect of an SPC is to extend the duration of patent protection by a period equal to the period that elapsed between patent application and the date the first marketing authorisation was obtained, but by no more than five years.[8] The original SPC Regulation contained specific transitional provisions for medicinal products patented before its entry into force under which Losec patents fell.[9]

The abuse

8. AstraZeneca was sanctioned under article 102 TFEU for abusing its dominant position, first, by making deliberate misrepresentations to the patent offices to obtain SPCs which it was not entitled to, or was entitled to for a shorter period of time; and

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5 Commission Decision (n 2), para 9.

6 Directive 65/65/EEC is now replaced by Directive 2001/83/EC of 6 November 2001 on the Community code relating to medicinal products for human use [2001] OJ L 311.

7 Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products [1992] OJ L182; it has been replaced by Regulation (EC) No 469/2009 of 6 May 2009 concerning the supplementary protection certificate for medicinal products [2009] OJ L152.

8 ibid, art 13(1).

9 ibid, art 19(1).

second, by requesting deregistration of the marketing authorisation for its Losec capsules in several Member States so that generic producers were unable to use the abridged market authorisation procedure. Both of these actions were deemed to be performed with an object of delaying generic market entry.

9. When it comes to the second abuse, a request for deregistration of marketing authorisations was considered to be going beyond the scope of the "competition on the merits", despite the conduct being otherwise legitimate, since no objective justification for AstraZeneca's behaviour was found other than the intention to deter generic entry. Although market entry by generic producers was not thus precluded, following deregistration of Losec capsules the abridged procedure was not available to generic producers willing to use that medicinal formulation.[10] While this was not explicitly spelt out in the judgment, deregistration of marketing authorisations for Losec capsules and replacing them with Losec MUPS (a different formulation covered by newer patent protection) was seen as part of the overall exclusionary strategy developed by AstraZeneca.

III The nature of the interaction between competition and patent policy at play in *AstraZeneca*

Is the interaction between competition and patent policies even at play here?

10. Having established the basic elements of the *AstraZeneca* case, one may wonder if this is really a case about the interaction between competition and patent policies. In fact, in its press releases the Commission distanced itself from the portrayal of the case as an intellectual property case. At the outset of the proceedings, in 2003, the Commission rejected the idea of describing AstraZeneca's actions as a misuse of intellectual property rights, preferring a characterisation of the abuse as a misuse of governmental procedures instead.[11] The then Commissioner Mario Monti asserted that "[t]his is not about the use or enforcement of patent rights which are necessary and even indispensable to foster a competitive European research-based pharmaceutical

[10] In Case C-223/01 *AstraZeneca A/S v Laegemiddelstyrelsen* [2003] ECR I-11809 the word 'marketed' in art 10 of the Directive 2001/83 of 6 November 20012 on the Community code relating to medicinal products for human use [2001] OJ L 311/67 was interpreted to require the reference product to be authorised.

[11] European Commission Press Release IP/03/1136 of 31 July 2003: "Commission warns AstraZeneca of preliminary findings in Losec antitrust investigation".

industry. It is about suspected misuses of the governmental systems and procedures...".[12]

11. Similarly, in 2012, following the CJEU's judgment, the Commission stated that the "judgment concerns two types of misuses of regulatory procedures and systems. It does not concern abuses or misuses of patents or other intellectual property rights".[13] These contentions might be seen as startling, especially in view of the fact that the Commission's attitude has not been consistent throughout the proceedings. In 2005, the Commission's press release announcing its decision against AstraZeneca talked of a fine for "misusing the patent system".[14] It is submitted that even if the principles established in that case could be easily applied outside the patent context, the particular context in which they were actually applied cannot be overlooked.

12. It is true that the first abuse concerned specifically the SPCs and not the use of the "core" patent procedures, but the existence of the SPCs cannot be separated from the patent system, since it is part of it.[15] Although it is true that patent offices do not again assess patentability criteria when considering SPC applications,[16] an SPC is a natural extension of the underlying patent. The purpose which it serves is identical to the underlying patent – to allow the innovator to recoup its R&D costs and to spur further innovation.[17] Also, the logic of the Commission's assertion that the principles established in the *AstraZeneca* case can be applied to various abuses of regulatory procedures also implies that it can be used for other abuses of the patent system.[18]

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12 ibid.

13 European Commission Memo MEMO/12/956 of 6 December 2012: "Antitrust: Commission welcomes Court of Justice judgment in the AstraZeneca case".

14 European Commission Press Release IP/05/737 of 15 June 2005: "Commission fines AstraZeneca €60 million for misusing patent system to delay market entry of competing generic drugs".

15 The now replaced Regulation (EC) 772/2004 of 27 April 2004 on the application of art 81(3) of the Treaty to categories of technology transfer agreements [2004] OJ L123/11, art 1(h) included SPCs within the definition of patents; the replacement Regulation (EU) 316/2014 of 21 March 2014 on the application of Article 101(3) of the Treaty on the Functioning of the European Union to categories of technology transfer agreements [2014] OJ L93/17 does not contain a definition of patents, but lists patents and SPCs separately as forms of 'technology rights' (art 1(b)).

16 In its Press Release of 2005 (IP/05/737), the Commission emphasised the fact that patent offices "were not obliged - as in normal patent assessments - to consider whether the products were innovative", which might be considered a curious statement in view of the fact that innovativeness of the drug in question was not questioned at any point during the proceedings.

17 Matteo Negrinotti, "Abuse of Regulatory Procedures in the Intellectual Property Context, the AstraZeneca Case", in Inge Govaere and Hanns Ullrich (eds), *Intellectual Property, market power and the public interest* (P.I.E Peter Lang 2008).

18 For as long as the undertaking is in a dominant position - this might not be the case when the undertaking is applying for a patent in respect of a breakthrough innovation (so a novel drug), since at this point it has not yet entered the market.

13. The second form of abuse committed by AstraZeneca, namely deregistration of the marketing authorisation, might at least at first sight be considered further removed from the issues at the borderline between competition and patent policies. All in all, the process of market authorisation is not part of the patent system and serves a different goal of health protection. Yet, the principles established in respect of this form of abuse can prove significant in the debate on misuse of patent procedures.[19] Indeed, Podszun goes so far as to describe this form of abuse as directly connected to and perhaps even interfering with patent law, since he characterises it as an abuse of property rights.[20] To him, the second form of abuse is closer to the debate at issue here, since he characterises the first form of abuse as an abuse of administrative procedures (thus concurring with the view of the Commission on the issue to that extent). Yet, both of these abuses can be described as using improper means or loopholes to expand patent protection beyond the period of time that the legislator deemed appropriate as a matter of patent policy.[21]

IV The Innovation Dimension of the *AstraZeneca* Case

14. The CJEU's decision in *AstraZeneca* has been described as establishing "the innovation paradigm as a pillar of competition law".[22] It is submitted here, however, that this enthusiasm might be premature. While the outcome of this individual case might be considered innovation-friendly, there are elements of the case that deserve a more critical assessment. These concern the position of antitrust law vis-à-vis patent law, the reasoning underlying the decision, the vision of the patent system entertained by the competition authorities and the scope of liability itself. They will be considered in turn.

The innovative thrust of the decision

15. By stepping in to curb abuse of the patent procedures, antitrust might be said to be working in line with or even reinforcing the patent policy. All in all, antitrust

19 Josef Drexl, "AstraZeneca and the EU Sector Inquiry: When Do Patent Filings Violate Competition Law?" (2012) Max Planck Institute for Intellectual Property and Competition Law Research Paper No. 12-02.

20 Rupprecht Podszun, "Can competition law repair patent law and administrative procedures? *AstraZeneca*" (2014) 51 Common Market Law Review 281.

21 Negrinotti (n 17), p 152.

22 Podszun (n 20), p 294.

intervention is aimed at sanctioning behaviours which are considered abusive also as a matter of patent policy. In doing so, antitrust enforcement helps to promote innovation as it ensures that patent holders can enjoy their exclusive rights only to the extent prescribed by the legislature. Beyond the scope of the patent, competition is considered to be required to promote innovation. Entry of generic products allows for further follow-on innovation to occur as well as it incentivises the originators to continue with their R&D efforts to develop new innovative products or processes. Here, unlike in the case of reverse payment settlements,[23] the two sub-systems of law are complementing each other in a beneficial manner to foster innovation.[24] Viewed in this way, the decision does not appear to be problematic. Indeed, it might be considered desirable to have a second filter in form of competition law to better ensure that exclusive rights are not abused. Accepting that antitrust is acting as a second filter, however, strongly suggests a regulatory failure on the part of the patent system that perhaps requires a fix. The ways in which abuse of the patent system can be addressed without help of competition rules are considered below in section VI.

Antitrust law as a "repair-it-all" service

16. At first sight, the outcome of the *AstraZeneca* case would appear to be a win-win situation in which it should not matter greatly that antitrust law effectively operates as a "repair-it-all" service for as long as frauds on the patent system are prevented (from a purely utilitarian point of view at least). However, the pro-innovativeness of the decision should not be assessed merely from the perspective of the outcome of a particular case. In deciding to intervene, the Commission and the Court made an important regulatory choice, one that will have an important bearing on future similar cases and the reasoning required therein. An interventionist approach on the part of the Commission puts more pressure on that competition body in terms of its own process, if a proper balancing of interests is to be ensured and if patent policy is not to be unduly undermined. The Commission's decision to intervene might be seen as a reflection of a more general policy of that competition authority and the CJEU that antitrust applies to regulated sectors in an ordinary manner, without providing any sort

[23] Considered in Chapter 3.
[24] Negrinotti (n 17), p 159.

of immunity.[25] Yet, the Commission's willingness to take up the *AstraZeneca* case in circumstances where the national patent authorities and national courts have the power and expertise to refuse SPCs applications which should not warrant a grant of the right, is very telling of the Commission's belief (or rather its lack) in the efficacy of the patent system. The availability of alternative remedies arguably takes the case one step away from *Deutsche Telecom*,[26] where the behaviour could have been considered legitimate outside the realms of antitrust and where the aim of antitrust intervention could be seen as correcting a national regulator - here it was clear that AstraZeneca's behaviour would be considered abusive also as a matter of patent law and general law on misrepresentation.

17. Yet, the Commission decided to step in, and in doing so it emphasised the limited discretion given to the patent offices[27] as well as their reliance on the data provided by the applicants. It considered that the availability of alternative remedies was not a sufficient reason to abstain from antitrust involvement. It emphasised the insufficiency of the available alternative remedies (i.e. of possible revocation of an SPC) from the competition policy perspective.[28] It pointed to the fact that revocation would require intensive litigation and that no sanctions would otherwise be available for failed attempts. In its decision the Commission specifically rejected an approach based on a distinction between existence and exercise of the patent, as advocated by AstraZeneca, and instead preferred an approach based on the competition on the merits. It seemed to have considered this approach to be non-intrusive, since it stated that "the laws of the Member States are not affected by qualifying as abusive misleading representations made in the context of applications for intellectual property rights."[29]

18. Yet, this approach effectively puts the Commission in a position of a repair-it-all service, and that stands true even if one accepts an argument that the Commission became involved not to prohibit said conduct *per se* but to prevent anticompetitive effects thereof.[30] This intrusive approach is not universally accepted across different competition authorities. For example, the Canadian Competition Bureau has in the past refused to take on board a similar case on the grounds that the patent regulatory

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25 Case C-280/08 P *Deutsche Telekom AG v Commission* [2010] ECR I-9555, taking a position different from that of the US Supreme Court: *Verizon Communications Inc. v. Law Offices of Curtis v. Trinko, LLP*, 540 U. S. 398 (2004).

26 ibid.

27 See eg Commission Decision C (2005) 1757 final of 15 June 2005, para 626.

28 ibid, paras 744-748.

29 ibid, para 741.

30 ibid, para 744.

framework already contained provisions designed to deal with that sort of matters and an additional antitrust intervention was not necessary.[31] The Canadian approach to inappropriate patent extension (the case concerned an allegation of evergreening)[32] and characterisation of the issue as a patent dispute was justified by the fact that its regulatory framework allows for patent 'linkage' whereby a patent holder who applied for a notice of compliance (equivalent of a market authorisation) might have a patent related to the medicinal product registered. A generic producer who wishes to use an abbreviated procedure must then serve a notice of allegation against the patentee.[33] The Canadian regulatory scheme resembles that used in the US,[34] with a notable difference being that a generic producer might sue for damages if it turns out that the innovator unjustifiably delayed its entry.[35] The list of registered patents is also audited *inter alia* for attempts of evergreening and entries might be refused.[36] Although the patent solution to the problem of inappropriate patent extention could be said to be more developed in Canada, it has been also subject to controversy for its heavy reliance on court battles, which are said to contribute to delays of generic entries.[37] Even if that is the case, a comparison with Canada further reinforces a view that the question of anticompetitiveness is closely related to the shape of the underlying regulatory framework.

19. It should be highlighted that an interventionist antitrust approach is a regulatory choice that needs not in itself go against the interests of innovation policy. Yet, it informs the way antitrust-patent interaction is viewed and affects the demands that are put on the decision-making process. An interventionist approach might indeed provide an opportunity and a forum in which to balance the policy interests of antitrust and the patent system. That, however, would require a recognition that protection of the needs

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31 Sophie Lawrance, Pat Treacy, "The Commission's *AstraZeneca* decision: delaying generic entry is an abuse of a dominant position" (2005) 1(1) Journal of Intellectual Property & Practice 7, p 8.

32 While it could be argued that the phenomenon of evergreening (see para 43) differs from the situation in *AstraZeneca* since it extends to situations which are perfectly legitimate as a matter of patent law, the circumstances bear some similarity, so much so that the *AstraZeneca* was also characterised by some commentators as an evergreening case, see Lawrance and Treacy (n 31).

33 A court then assesses only the notice of allegation, but does not decide on patent validity or infringement, making further proceedings possible, see William L Vanveen, "Pharmaceuticals and Competition Law, Regulatory Context, Settlement Agreements and More" (2009) Canadian Bar Association Competition Law Fall Conference, available at http://www.cba.org/cba/cle/PDF/COMP09_Vanveen_paper.pdf (accessed 15 February 2017), p 6.

34 For the details on the operation of the Hatch-Waxaman Act see ch 3.

35 Under s 8 of the PM-NOC Regulations (Patented Medicines (Notice of Complaince) Regulations) under the Patent Act.

36 Thomas A Faunce and Joel Lexchin, "'Linkage' pharmaceutical evergreeing in Canada and Australia" (2007) 4(8) Australia and New Zealand Health Policy, p 2.

37 ibid.

of patent policy is in itself in the interest of competition policy. As it will be seen below, antitrust analysis as performed in *AstraZeneca* does not reach that far. Whether it is necessary, or indeed constitutes an optimal solution from the perspective of division of tasks between two sets of regulatory bodies could be considered debatable in light of the fact that a solution to the problem of low detection levels of undeserving patent/SPC applications would seem to lie more naturally within the realm of the patent system. It is the latter institution that has the necessary expertise and more sophisticated tools to distinguish legitimate conduct in that sphere from an inappropriate one. The problem of lack of a strong sanctioning system on the part of patent authorities could be viewed as a concern more well-suited to legislative action. In that sense, using antitrust law as a tool to repair the alleged deficiencies of the patent system, or to push for eliminating those (*signalling*), might not be considered appropriate, since the same or better result might be achievable in a more straightforward way. On the other hand, the fragmentation of the European patent system might work as a partial justification for the Commission's practical approach. This interventionist approach would, however, need to be matched by a more in-depth scrutiny of the impact on the patent system that establishing antitrust liability on particular terms might have if incentives to innovate were not to be harmed. As the sections below will reveal, the approach of the Commission and the CJEU might not have been entirely satisfactory in that respect.

Reasoning underlying the decisions

20. Podszun commends the *AstraZeneca* case for the re-establishment of innovation as a yardstick against which conduct is measured,[38] but a closer look at the case as it proceeded from the investigation stage to the judgment of the CJEU appears to shake that conviction in terms of how much attention was actually paid to the innovation angle in the deliberations of the Commission and the Courts. The difficulty that pertains to the assessment of reasoning undermining any decision lies with the fact that some of the considerations that informed the authority's approach are not visible on the face of the documents available to the public. Yet, an omission can sometimes be equally telling as it suggests that a given factor was not crucial to the reasoning underlying the decision in question. For this reason, it is interesting to examine the

[38] Podszun (n 20), pp 293-294.

reasoning that led to the judgment in the *AstraZeneca* case. As already mentioned above, greater competition law involvement in patent issues would suggest a corresponding need for a parallel move towards more in-depth treatment of the substantive policy issues at play at the competition-patent intersection as dictated by the needs of the innovation policy. Yet, no such move has been witnessed in *AstraZeneca*.

21. Starting with the Commission Decision from 2005, very little in that document suggests that innovation is key to the case. The word 'innovation' itself does not feature very often in the Decision, and if so, it is mostly in connection to the question of the definition of the market, rather than wider policy questions relating to the appropriateness of antitrust intervention or the anticompetitiveness of the conduct at play.

22. In fact, the better part of the decision concerns factual aspects of the case, with the Commission analysing a number of documents to establish that AstraZeneca truly pursued an intentional anti-competitive strategy. While establishing beyond reasonable doubt the factual grounds on which the case stands is a prerequisite of any case, it might be considered disappointing that the document does not contain a more extensive discussion of the rationale for intervention. Indeed, one could expect a more open exposition of the policy behind that determination, given the novelty of the issue.

23. Lack of openness on the part of the Commission about the policy considerations at play can be explained by the double role it plays as a competition policy maker and prosecutor in individual cases. Including in its decisions elements that are not strictly necessary for the conclusions it reached could weaken its case and open decisions to challenge (not to mention being more costly on the Commission's resources), so from a more pragmatic point of view it is understandable why the Commission avoids the more open-ended policy discussions. However, from the point of view of policy creation, it leaves a lot to be desired. One way out of this conundrum would be to be more open about its approach in other policy documents. On the other hand, such documents or guidelines do not allow for consideration of the issues in an equally focused manner as individual cases do and can be equally affected by the Commission's double role.

24. Going back to whatever little can be established from the decision in relation to innovation, the theory of harm ran there was that AstraZeneca's conduct was

anticompetitive because it delayed generic entry.[39] Now, a delay of generic entry might be considered undesirable for various reasons. From the innovation perspective, AstraZeneca's conduct might be considered anticompetitive because generic entrants themselves might be involved in innovative activity for example in respect of processes used for obtaining a medicinal product like Losec. Timely generic entry also pushes the originator to continue their R&D efforts in hope of inventing a new innovative drug for which they might be able to charge higher prices thanks to patent protection.

25. Yet, this does not appear to be the rationale underlying the Commission's condemnation of causing a delay of generic entry. Although the Commission decision does not contain an explicit explanation as to why delay of generic entry is injurious, it devotes three sections[40] to explaining the cost savings for national health systems and for the consumers stemming from generic entry. It talks of "cheaper generic products"[41] and "cost containment measures"[42] and explains that:

> The rationale behind the pro-generic cost-containment measures is the fact that prices for generic products are often much lower (typically by 20-50%) compared to the corresponding original medicines and that such lower-priced generic products entail savings for the national health systems (and, thereby, the taxpayers and contributors to insurance schemes), which - through the reimbursement systems - bear the bulk of the cost for medicines.[43]

26. On the other hand, nowhere in the decision one can find references to the role of generic market entrants in incentivising competition on innovation. This apparent reliance on a theory of harm that concentrates on effects on prices of the conduct in question could be attributable to the acute political pressure pertaining to the pharmaceutical sector to bring about immediate consumer benefits in form of affordable medicines.[44] This without doubts is a valid consideration to be had, but it

39 See for example para 762 of the Commission decision (n 2).
40 ibid, paras 112-138.
41 ibid, para 113.
42 ibid, para 114.
43 ibid, para 116, footnotes omitted.
44 Dimitris Xenos, "Limiting the IPRs of the Pharmaceutical Companies through EU Competition Law: The First Crack in the Wall" (2011) 8(1) SCRIPT*ed* 92, p 96.

hardly establishes innovation as key to the analysis. While on the facts in *AstraZeneca* short-term considerations could have pointed in the same direction as innovation policy demands, it is suggested here that the Commission was not necessarily guided by that latter consideration. This is significant for in terms of wider principle it creates an acute risk that a proper balancing exercise aimed at promoting innovation is not performed. As it will be seen below,[45] it also created deficiencies in the decision-making process in the case itself, in so far as it established a wider precedent going beyond the facts of the case.

27. The General Court's judgment, although the longest by page count, contains almost equally little on the innovation angle of the issue. While admittedly the Court addressed the argument that the judgment would have a freezing effect on patent applications, it did so rather swiftly in a single short paragraph.[46] It did so by turning the argument upside down and saying that misuse of the patent system itself reduces the incentive to innovate since it enables companies to enjoy patent protection for periods longer than envisaged by the legislator. Although this statement is hardly controversial, it falls short of addressing directly what was at the heart of the challenge to the Commission's reasoning based on possible adverse effects on the patent system caused by establishing antitrust liability (on such wide terms). In its reasoning the Court limited itself to the factual scenario of the case before it, even though the argument as presented by the applicants expressly invited the Court to pronounce on the wider principles at stake.[47] The Commission's counter-argument, as presented in the judgment, was actually a more comprehensive and a more direct response. The Commission countered by denying that "simple inaccuracies, negligent misstatements or the expression of debatable opinions" would be regarded as infringements of article 102.[48] Thus, the Commission came closer to delineating the scope of the concept of abuse of the patent system, a task vital from the innovation perspective. Yet, the Court did not proceed to expressly endorse this statement or elaborate on the issue.

28. Similar observations can be made of the judgment of the Court of Justice. Its failure to delineate the limits of antitrust intervention is illustrative of the failure to embrace the innovation dimension. Even if the outcome of this particular case can on the whole be considered advantageous from the innovation perspective, the reasoning process of the

45 See section concerning the scope of liability, para 34 ff.
46 Commission decision (n 2), para 367.
47 Para 312.
48 Para 338.

Court leaves much to be desired. Admittedly, judicial economy calls for a succinct way of deciding cases and against elaborate policy statements in the Courts' decisions. Equally, the role of the Court in reviewing the Commission's decisions is also limited. However, considering the fact that it was a novel, precedent-setting case that was predicted to have a potentially significant impact on the functioning of patent intensive industries, one would expect at least an acknowledgement of the delicate balance of interests that might be at play. With these issues brought expressly to the fore by the defendants, the Court had a good opportunity to embrace the innovation dimension of the problem and address questions of wider principle.

29. In a like manner, the exposition of the case by the Advocate General[49] sticks closely to the points under appeal and does not venture into wider policy questions. It neither addresses the issue of the regulatory approach applied nor the wider normative questions pertaining to the scope of the concept of abuse as applying in the misuse of patent context. It merely states that in his view the approach applied by the General Court does not set a low threshold of abuse and that it will not have a chilling effect on IPR applications by increasing regulatory burden on companies.[50] No reasons for this opinion, however, are provided. This might be seen as particularly regrettable, since Advocate General's Opinions provide perhaps the best opportunity in the course of the CJEU judicial process for an open discussion of the policy issues at stake in a case. Yet, the innovation policy angle of the case was not openly discussed in any detail.

The vision of the patent system as revealed from the case

30. Apart from the policy decision to get involved with the issue and a reasoning based on short-term considerations, the approach of the Commission and the Court to the patent system is also discernible in the specific arguments examined in that case and in what could be considered *obiter* statements. To give an example, the Commission considered formulation patents to be generally weaker than original substance patents since they are easier to circumvent.[51] Even if this statement was not decisive for the case at hand, it is still informative of the Commission's approach to patent law and might prove influential in future cases. Similar statements were made as part of the

49 Opinion of Advocate General Mazak, delivered on 15 May 2012.

50 ibid, para 51.

51 Commission decision (n 2), paras 14 and 16. The term 'formulation patent' refers to a patent over a particular "mixtures of active agents and other substances which promote the activity of the medicine by, for example, enhancing absorption in the body" (Pharmaceutical Sector Inquiry Report, para 138).

Sector Inquiry, where the Commission talked of "secondary patents".[52] However, while the Commission seems to become more and more at ease with the idea, the distinction between patents of different strength (and thus by implication deserving a different level of protection) finds no foundation in patent law and can be potentially damaging to patent policy, which in turn might affect its pro-innovation design.

31. The worrying thing about this apparent easiness with which the Commission is prepared to pass judgment on the elements of the patent system is that these statements are not supported by an in-depth scrutiny of the issue. Consequently, in absence of an in-depth analysis, these statements amount to nothing more than well-rehearsed clichés that are unsupported by any evidence and which might very well be premised on a limited understanding of the patent system. This is not to say that all patents are in practical terms of the same strength (as on the facts a patent claim might be of a limited nature) or that they should be treated equally. Indeed, there might be good reasons for distinguishing between different forms of patents, but so far the Commission failed to persuasively show that this is or should be the case. Any such conclusion on the part of the Commission or the CJEU would need to be a result of careful analysis of patent authorities' practice, since these are the bodies who should play a leading role in establishing a policy on the point. In the European setting the competition authorities might simply lack jurisdiction to make normative value judgements on the issue.

32. Even if one accepts an utilitarian argument that antitrust can sometimes achieve what is impossible as a matter of patent policy (for example because it is difficult to achieve legislative change), any such modifications to the dynamics of the system should be a result of a conscious and informed decision-making. There is a lot to be gained from having a good grasp of the realities of the patent system since it sets the conditions of competition in innovation. In this way, the Commission and the Court would avoid making inadvertent changes to the dynamics of patents through antitrust involvement. Affecting patent law through the back door on a basis of untested ideas might have negative consequences for both competition and innovation.

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[52] The Commission actually denies that it treats those "secondary patents" as of lower value (see eg para 20 or fn 580 of the final Sector Inquiry Report), but this negative connotation can be inferred from the way it approaches those patents in the Report.

What constitutes abuse?

33. One further problem with *AstraZeneca* arises in connection to the question of limits of antitrust intervention. In its reasoning the Court did not limit the principle established by its judgment to cases of fraud. In fact, the case leaves a lot of uncertainty as to the contours of the new form of anticompetitive abuse. As argued by the parties in the case, this could potentially have a chilling effect on patent applications and thus undermine the pro-innovative thrust of the patent system. Any such consequence would be flowing from excessive cautiousness on the part of the (would be) patent holders stemming from the fear of antitrust liability. Thus, arguably, a pro-innovation approach would require the court to proceed cautiously and to carefully delineate its theory of harm in light of the possible adverse impact of an unclear decision on the patent system.

34. In its decision the Court relied on previous case-law to emphasise that abuse is an objective concept and that proof of bad intent was not required, although a relevant circumstance.[53] Nevertheless, it found that the abuse in the case before it consisted of a deliberate and highly misleading strategy to delay generic market entry, which makes it difficult to determine what in absence of intentional conduct constitutes abuse. On the facts, AstraZeneca's belief in the alternative interpretation of the relevant provision was rejected,[54] but the Court considered that the reasonableness of AstraZeneca's interpretation was not even an issue in the proceedings in light of the highly misleading representations it made and the fact that an abuse is an objective concept. However, it is not difficult to imagine a counterfactual hypothetical scenario in which a company actually misinterprets the law and at the same time wrongly assumes that the patent authorities share its view. Should it be afraid of antitrust liability? Going one step further, should a patent applicant who wrongly believes in the strength of its application have any reason to be alarmed?[55] These questions are left unanswered as a matter of EU antitrust law.

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53 Case C 457/10 P, para 74; case T-321/05, paras 356-359.

54 AstraZeneca tried to defend itself by claiming that it relied on a particular interpretation of the SPC Regulation, one that allowed it to obtain an SPC based on effective marketing date, effective marketing date being the date when the pricing lists are published. In some Member States a marketing authorisation is not sufficient to put medicinal products on the market, first, the product needs to be put on the pricing list. However, the Court held that AstraZeneca failed in its "special responsibility" as a dominant player by not disclosing its alternative interpretation to the patent offices and in any case its behaviour has been inconsistent, which suggested that reliance on this explanation was just a cover up for its fraudulent intentions.

55 Provided they were in a position of dominance.

35. In addition, reliance on the concept of abuse as an objective concept is combined with the standard of "competition on the merits", which in itself could be criticised for being vague and lacking in analytical vigour that would allow for distinguishing between "normal" use of the patent system from anticompetitive conduct.[56] There is nothing to suggest that the Commission's or the Court's approach to what constitutes "competition on the merits" coincides with what is considered legitimate conduct as a matter of patent law or indeed that the competition bodies have a way of knowing that in situations that might be more nuanced than the problem faced in *AstraZeneca*.

36. Furthermore, for the purposes of establishing antitrust liability in *AstraZeneca* it did not matter that SPCs were not enforced or that some of them were revoked before the basic patent has expired. While the reach of the case could still be qualified in the future, it would appear that the EU approach departs from that established in the US in that respect. Similarly to the position taken in the EU, the US Supreme Court has in the past condemned as anticompetitive wilful misrepresentations to the patent office.[57] However, in contrast with the EU, the US courts require (1) a wilful fraud on the part of the defendant, and (2) for there to be an actual attempt at enforcing the patent.[58] So, the contours of the antitrust intervention in cases of abuse of the patent system are not only more clearly delineated, but also more limited.

37. Indeed, separate Opinion of Justice Harlan (concurring) in the *Walker Process Equipment v Food Machinery* case (the case in which the principle of antitrust liability for the abuse of the patent procedures was established) confirms the wariness and cautiousness with which the Court proceeded in that case. Appreciating the controversy which the case could have raised, Justice Harlan was careful to clarify the reach of the ruling. In doing so he recognised that to hold "that private antitrust suits might also 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, might well chill the disclosure of inventions through the obtaining of a patent..."

38. It is suggested that the approach adopted by Justice Harlan is to be preferred. His comments are relevant in the European context regardless of the fact that the US law

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56 See further ch 10.

57 *Walker Process Eqpt. Co. Inc. v Food Mach & Chem. Corp.* 382 US 172.

58 The second requirement stems from the necessity to establish all elements of §2 monopolisation charge; see Herbert Hovenkamp, *Federal Antitrust Policy - the Law of Competition and its Practice* (Thomson West 2005), p 328.

on monopolisation operates differently than abuse of a dominant position under article 102. This is not only because a standard of proof requiring anything less than outright fraud or a wilful misrepresentation on the patent system would have a chilling effect on innovators, but also because any excessive uncertainty pertaining to the extent of liability might have a similar effect.[59] The failure on the part of the Court to delineate the scope of its judgment might be considered one of the biggest drawbacks of the *AstraZeneca* decision. In light of the previous US experience, it was to be expected that questions about the scope of the judgment would follow. Even if the Commission wanted to leave open the question of what might constitute abuse of the patent system in general, given the unpredictability of the patent holders' activity which might cover a wide range of behaviours, it still could have been more precise in establishing the basis of AstraZeneca's liability. While it is difficult to state with any degree of certainty whether it was a conscious decision on the part of the Court not to clarify this point, as a matter of wider policy it might be considered regrettable for even if we accept that the law develops in an evolutionary way through consecutive precedents, leaving the basis of liability unclear makes the decision unsatisfactory, not just from the innovation perspective. Also, as a more general observation, the resulting uncertainty might be seen as one of the drawbacks of adopting an antitrust solution to the problem of patent abuse.[60]

39. Doing "just enough" and allowing the questions of principle to be left to be developed in future cases might not be sufficient in an area as delicate and as important as this one. Even if we accept the limited role of the Court in reviewing the Commission's decision, the argument still applies in respect of the Commission's decisional practice. It might also be considered surprising, given the regulatory choice made by the Court/Commission to get involved in the first place. The intrusiveness of the competition policy approach is not matched by a willingness to embrace the true depth of the issue at stake. In effect, the innovation dimension pertaining to the question of the form and extent of competition intervention in patent policy is side-stepped and not addressed at all. Even if it is just a question of not addressing the issue openly, it still creates an impression that the Court is moving aimlessly. An omission of this kind makes it difficult to defend the case as innovation-friendly.

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59 David W Hull, "The application of EU Competition Law in the Pharmaceutical Sector" (2011) 2(5) Journal of European Competition Law and Practice 480, p 485.

60 See Thorsten Käseberg, *Intellectual Property, Antitrust and Cumulative Innovation in the EU and the US* (Hart Publishing 2012), p 62.

V The potential reach of *AstraZeneca*

40. The factual situation faced in *AstraZeneca* was rather unique, in fact in all likelihood it will not repeat itself because of the changes in the law that have occurred since.[61] In so far as the first abuse goes, the misrepresentations concerned the conditions for obtaining an SPC under transitory provisions of the SPC Regulation that are no longer in use.[62] The second abuse, on the other hand, would no longer be possible because of the changes in the legislation on marketing authorisations. As the law now stands, a deregistration of a marketing authorisation no longer precludes abridged procedure applications, the clinical data submitted as part of the original application can be relied upon by the generic producers following the expiry of the regulatory data protection (RDP) for as long as the reference product was once marketed in one of the EU Member States.[63]

41. Should this be taken to be a further suggestion that the Commission's reaction was "overzealous"?[64] Not necessarily. Despite the possibility of confining *AstraZeneca* to its facts, this is unlikely to be so. The only question is how far-reaching exactly the implications of the case will prove to be. As already discussed above, the Court left many questions open, including one about the degree of fault. One thing is certain though: for conduct to fall within article 102, the undertaking must be in a dominant position on the market in question. This condition is unlikely to be met at the point of applying for a patent since at this point a producer of a novel product has not yet entered the market. This is true at least in case of breakthrough innovation, so for example novel pharmaceutical products, but not necessarily in respect of process patents relating to an already existing substance. The effect is to take a great chunk of patent applications outside the remit of the competition system. This conclusion, however, is dependent on the approach to the timing of the abuse. In *AstraZeneca* it was established that the abuse took place as soon as the undertaking made misrepresentations to the patent offices. However, if an abuse were to be established at

61 Drexl (n 19), p 2.

62 Art 19, Council Regulation No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products [1992] OJ L 182/1.

63 Directive 2004/27 of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use [2004] OJ L 136/34.

64 Maria Isabel Manly, Anna Wray, "New pitfall for the pharmaceutical industry" (2006) 1(4) Journal of Intellectual Law & Practice 266, p 270; noting the ambiguity of the SPC legislation.

the point of patent enforcement, it could make the scope of application of *AstraZeneca* much wider.

Other forms of patent misuse

42. Furthermore, the reach of the case might not be limited to fraudulent or misleading representations to the patent offices. If approached in a principled way, the practical significance of *AstraZeneca* can potentially be very far reaching. The Pharmaceutical Sector Inquiry report provides some suggestions as to what type of conduct might become an object of the Commission's attention in the future. The practices identified in the pharmaceutical "tool-box" of strategies are certainly viewed with suspicion by the Commission, notwithstanding the fact that it has not formally named them as anticompetitive. Although we are yet to see how far the Commission (and the Court) is willing to push the boundary of article 102, some of these developments could be worrying from the innovation perspective.

43. Unlike the conduct condemned in *AstraZeneca*, some of the "toolbox" strategies, as identified by the Commission in the sector inquiry, are perfectly legitimate as a matter of patent law. Among practices that could potentially be considered anticompetitive misuse of the patent system by the Commission are creation of patent clusters,[65] (whereby a patent owner has a number of patent rights over the same invention, thus making patent challenge more difficult for generic producers) and the so called evergreening (prolonging the effective life of a patent protection through introduction of formulation patents towards the end of a life cycle of the original patent).[66]

44. While these practices can be problematic, since they expand the patent holders' exclusivity (potentially beyond the limits justified by patent policy), their inclusion within the group of those considered to be anticompetitive would raise further regulatory problems, going beyond and above those faced in *AstraZeneca*. This is because the conduct in question goes to the very core of the existence of patent rights.[67] To conclude that such conduct is anticompetitive would be to openly negate the presumption that patent law is in principle pro-innovative – a further development from *AstraZeneca*, which as such does not negate the pro-innovative function of the

65 See European Commission, Pharmaceutical Sector Inquiry: Final Report (8 July 2009), C.2.1.

66 ibid, C.2.6; see para 167 of the Report for a full list of strategies identified by the Commission as potentially problematic.

67 Mario Siragusa, "The EU Pharmaceutical Sector Inquiry. New forms of Abuse and Article 102 TFEU", in Giandonato Caggiano, Gabriella Muscolo and Marina Tavassi (eds), *Competition Law and Intellectual Property: A European Perspective* (Kluwer Law International 2012), p 183.

patent system.[68] Such move would be very difficult to defend in terms of the deliberation process. It would put into question the parties' ability to rely on the pro-innovation rationale of the patent right to justify their conduct.[69] This could be considered unprecedented, for even refusals to supply and reverse payment settlement cases could be explained as sanctioning only a particular way in which a patent right is exercised rather than the existence of the patent right itself. Also, while refusals to supply must meet the "exceptional circumstances" threshold, it might be difficult to establish a similar limiting principle in case of patent clusters or evergreening. In those circumstances, distinguishing lawful from the unlawful behaviour could be challenging, if not impossible.

45. It is at this point that the second abuse from *AstraZeneca* becomes significant: the deregistration of marketing authorisations was perfectly legitimate outside the realm of competition law, yet it was still found anticompetitive. Could this suggest that the same approach could be applied in the future to patent clusters or to evergreening practices? Of course, it would be possible to argue that such practices go against the underlying objectives of patent law, but it is questionable whether the competition authorities are in a position to appropriately assess that. This is especially so in light of the experience so far, whereby the Commission and the Courts are not prepared to go into the details of the policy dilemma at play.

Lessons to be learnt from Pfizer

46. Failure to delimit the scope of *AstraZeneca* made it possible to speculate about the reach of competition law as against patent practices; a discussion which in itself might have a chilling effect on the incentives of would-be inventors. A threat of competition liability together with a belief that a patent right is worth less since it cannot be utilized in certain ways that were previously considered available to patent holders must have an effect on the incentives to innovate. While it is possible to deliberate how significant that chilling effect might actually be, it should be borne in mind that the above discussion does not concern just a mere hypothetical possibility: the national competition authorities/courts have been influenced by the Commission's performance, as the *Pfizer* case shows.

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68 Drexl (n 19), p 8.

69 ibid: "Concerning the interface with patent law, a most important issue in applying Article 102 TFEU to patent filing is whether the applicant can rely on the pro-innovation rationale of patent law in order to justify its conduct."

47. In 2012 the Italian Antitrust Authority (IAA), fined Pfizer for a violation of article 102 TFEU consisting of misuse of the patent system.[70] According to IAA, Pfizer acted anticompetitively by obtaining a divisional patent,[71] which allowed it to mitigate the losses caused by missing the deadline for applying for an SPC based on the parent patent. This strategy was said to be aimed at inappropriately delaying generic market entry by misusing the administrative procedures at place. By sanctioning Pfizer, IAA further extended the reach of *AstraZeneca* to conduct which is legitimate as a matter of patent law without clearly identifying the elements of Pfizer's conduct that were actually abusive (i.e. going beyond the "competition on the merits"). In doing so, it actually misread the purpose of a divisional patent, which contrary to IAA's understanding, is not meant to involve any additional innovation.[72]

48. The IAA's misguided reading of patent law has been corrected by the regional court, but then the Italian Supreme Court reversed that ruling, re-establishing the position taken by the IAA.[73] While the regional Court was of the opinion that the IAA misinterpreted *AstraZeneca*, the latter tribunal thought it was in line with it. This is despite the fact that in the meantime the EPO board upheld the divisional patent as valid.[74] According to the Supreme Administrative Court the "results of the application procedure are not significant, as well as the timing of the application before EPO and the effective content of the claims accepted with the divisional patent, since the legal field of patent protection of inventions is different from the one of competition law."[75]

49. It is submitted here that this outright denial of relevance of patent policy to the finding that Pfizer violated competition law misses the point of the policy issue at play. Unless one rejects the pro-innovation function of patent law, the confirmation of validity of

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70 Decision of the Italian Antitrust Authority of 11 January 2012, No. 23194, Case A431 - *Radiopharm/Pfizer*.

71 Where a parent (original) patent application concerns more than one invention (i.e. lacks unity of invention) it may be split into two or more divisional applications which preserve the same priority date as the parent application. Splitting of the application in the event of lack of unity of invention is required by art 4G of the Paris Convention.

72 Gianni De Stefano, "Tough Enforcement of Unilateral Conduct at the National Level: Italian Antitrust Authority Sancions Bayer and Pfizer for Abuse of Dominant Position (aka AstraZeneca Ruling and Essential Facility Doctrine in Italian Sauce" (2012) 3(4) Journal of European Competition Law & Practice 396, p 400, noting that even the Commission Sector Inquiry report recognises that division patents "cannot extend the content of the original application" (p 11 of the Executive Summary of the Pharmaceutical Sector Inquiry Report).

73 Decision of the Supreme Administrative Court (Consiglio di Stato) of 12 February 2014 – Case No. 9181/2012 Autorita` Garante della Concorrenza e del Mercato, Ratiopharm Italia s.r.l. and others v. Pfizer Italia s.r.l., Pfizer Health AB and Pfizer Inc.

74 EPO decisions do not preclude challenges to validity before national courts, since patents are national rights. Nevertheless, the decisions of the EPO can be influential on the national courts' decisions.

75 Translation by Marco Bellia, "Italy, Pfizer", IIC, 15 October 2014.

the divisional patent by the EPO board was strongly suggestive of the fact that Pfizer was simply using a lawful mechanism established by the patent law to promote innovation (the proper functioning of which contributes to consumer welfare), rather than pursuing some "artificial" strategy as claimed by the IAA.[76]

50. While the Court and IAA both tried to emphasise the abusive *strategy* of Pfizer and that Pfizer's particular mode of exercising its rights caused an "imbalance between the benefit for the right holder and the cost for the other party",[77] neither body managed to pin point what distinguished Pfizer's conduct from normal "competition on the merits".[78] All in all, it is in the very nature of patent rights to give the patent holder an imbalance causing advantage. Inability to establish specifically what it was about the Pfizer's exercise of a right that was anticompetitive suggests that it is the very existence of a right that was found objectionable.

51. From the innovation perspective, both the outcome and the deliberation process that led to it can be described as worrisome.[79] In fact, it does not appear that the Italian Court was guided by dynamic competition requirements at all in giving its decision, for it underlined not only the effect on the generic entries but also on the Italian NHS.[80] This conclusion is reinforced by the fact that it treated competition law and patent law as completely separate spheres, thereby effectively putting them in conflict. This shows that the role of competition law in this context was viewed by the court as limited to facilitating generic entry rather than securing results which are optimal from the innovation perspective, which requires careful balancing of the interests at stake and awareness of the dynamic interaction between competition and patent policies.

52. The judgment appears to be a realisation of the worst fears expressed in connection to *AstraZeneca*. It takes a very wide reading of that case, mixing together the first and the second limb of abuse in that case, leading to a result which is potentially dangerous from the innovation perspective. To say that the validity of the divisional patent was not relevant to the finding of anticompetitiveness in the circumstances of the case is to misunderstand the nature of the problem. In effect, the case negates the pro-innovation

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76 Damien Geradin, "When Competition Law Analysis Goes Wrong - the Italian Pfizer/Pharmacia Case" (2014) available at http://ssrn.com/abstract=2393383, p 14.

77 Translation by Marco Bellia, 'Italy, Pfizer', IIC, 15 October 2014.

78 The vagueness of the standard for deciding which conduct violates article 102 TFEU and which does not has been heavily criticized by the commentators; see, for example, Damien Geradin (n 77) , p 3: "Following this unreasoned decision, pharmaceutical companies and their counsel face an impossible task of assessing which IP strategies are compatible with competition law."

79 Lazio Regional Court bluntly described the IAA's decision as "illogical" (ibid, p 3).

80 ibid, concurring.

presumption of the patent system without engaging in the balancing exercise that would be consequently required. The resulting inability to distinguish between lawful and unlawful conduct clearly undermines the patent system, potentially to the detriment of innovation.

53. More importantly, the case shows how suggestive the Sector Inquiry proved to be, since divisional patenting is also discussed there as one of the "toolbox" strategies.[81] It also illustrates how widely *AstraZeneca* can be interpreted. This in turn, suggests that practices like creation of patent clusters and evergreening might be next in line for competition scrutiny. Thus, the discussion of the chilling effect on the incentives resulting from *AstraZeneca* becomes a not so trivial one. Following the judgment in *Pfizer*, it would seem that the fears entertained by the patent holders after *AstraZeneca* might indeed be very real. Even if the Commission/CJEU in the future decide not to follow *Pfizer*'s line of reasoning, it might be that the damage was already done when the *AstraZeneca* judgment was handed down. It could be argued that it enabled the outcome in *Pfizer* by failing to establish the limits and a clear basis for antitrust intervention for cases of patent misuse. The developments on the national plane following *AstraZeneca* demonstrate how much uncertainty it has introduced. The Pfizer case is just one illustration of the resulting uncertainty, but is not the only one. Other examples can be found also at the Commission level. To give just one, the *Boehringer* investigation, which was ultimately settled, could also suggest that the Commission might be willing to take a wide interpretation of patent misuse.[82] The case concerned the question whether Boehringer tried to prevent its competitors from entering the market by applying for unmeritorious 'blocking' patents. Although it did not provide an opportunity to hear a full exposition of the Commission's position on the issue, the investigation further added to the fears of patent holders and patent holders-to-be since it concerned an established practice followed in the pharmaceutical sector.[83] We might only hope that an opportunity for clarification will come soon and that next time a more serious thought will be given to the innovation angle.

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81 In the Sector Inquiry Report the Commission concentrated on a different aspect of divisional filing (i.e. the extension of the period of patent examination), so the Italian authorities' approach might be actually a misreading of the European position on the point. The IAA expressly relied on the Sector Inquiry Report in its decision, see p 178 of that decision.

82 European Commission Press Release IP/11/842 of 6 July 2011, "Antitrust: Commission welcomes improved market entry for lung disease treatments".

83 Podszun (n 20), p 292.

VII Addressing the problem of abuse of the patent system outside the realm of antitrust

54. The abuse of the patent system identified in *AstraZeneca* was a pre-grant abuse, which could be characterised as an abuse against the users (generic producers) as well as against the rationale of the patent system itself. The fact that it was a pre-grant abuse distinguishes it from other patent cases considered by the Commission and the CJEU which all concerned strategic use of patents. This direct connection to the patent application process would suggest that the EPO and the national patent offices might be better placed to discover and to handle cases of abuse. Yet, it appears that the possibilities for tackling abuse by the EPO are rather limited. The only remedy that the EPO has at its disposal is the refusal of a grant of a right, with the EPC containing no provisions covering instances of abuse.[84] Furthermore, the EPO's reliance on the information provided by the applicants reduces the chances that any irregularity in the application will be discovered. Private parties are allowed to bring opposition proceedings, but these need to be based on one of the three technical grounds specified in article 100 EPC.[85] These would probably prove insufficient to guard against situations like the one in *AstraZeneca* even if the misrepresentations were known to the generic producers.

55. Equally, general national law provisions on the abuse of rights might prove to be unsatisfactory. The notion of an abuse of rights is commonly known across the European jurisdictions, whether stemming from equity (in the common law tradition) or grounded in the requirement to act in good faith (in the civil law tradition).[86] While there appears to be nothing that would as a matter of principle restrict the application of that doctrine to patent cases,[87] as the name suggests, it is usually applied in respect

84 The only cases of abuse of procedure considered by the Examining Boards at the EPO to date concerned submitting evidence not in accordance with the regulations.

85 These are that: (a) the subject-matter of the European patent is not patentable under Articles 52 to 57; (b) the European patent does not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art; (c) the subject-matter of the European patent extends beyond the content of the application as filed, or, if the patent was granted on a divisional application or on a new application filed under Article 61, beyond the content of the earlier application as filed.

86 See e.g. Belgium: art 1134 § 3 of the Belgian Civil Code ('Rechtsmisbruik'); Germany: art 242 of the German Civil code ('Rechtsmissbrauch'); France: Cass. req., pourvoi no 00-02378, 3 august 1915 ('l'abus social' and 'l'abus-intention-de-nuire').

87 In Germany the abuse of right principle has been applied in a case concernning the use of a research exemption in patent law: Michelangelo Temmerman, "The Legal Notion of Abuse of Patent Rights" (2011) nccr trade regulaton swiss national centre of competence in research Working Paper No 2011/23, p 9.

of inappropriate or illegitimate use of already existing rights.[88] Also, it can only be applied as a defence and does not lead to a (*de facto* or actual) invalidation of the patent, but rather would need to be considered in each infringement case anew. At the same time, article 48 § 1 of the TRIPS agreement obliges member states to ensure that a party wrongfully enjoined or restrained by abusive enforcement procedures be provided with adequate compensation for the injury suffered because of the abuse.[89] While the types of abuse mentioned in article 40 § 2 TRIPS concern abusive use post-dating patent grant, there appears to be nothing in the wording of that Agreement that would suggest that abuses that occurred pre-grant should be excluded.

56. The same can be said of the US doctrine of misuse of patents.[90] It has been developed by the courts as an equitable doctrine, used against the patent holder attempts to "impermissibly broaden the 'physical or temporal' scope of the patent grant with anticompetitive effect".[91] It has been, however, largely applied in respect of patent use (by using the defence the defendant admits having infringed the patent), in particular in respect of licensing agreements.[92] The defendants in the US have, however, also the option to rely on the concept of 'inequitable conduct' to defend themselves against actions concerning a patent that results from a failure of the applicant in a duty of good faith towards the US Patent and Trademark Office (USPTO).[93] While the effect is to achieve permanent unenforceability of the patent, the conditions for succeeding with this defence have been construed rather strictly.[94] There exists also no clear European equivalent of the doctrine that could have been applied in the patenting context. The UK equivalent of the US doctrine of patent misuse, as enshrined in section 44 of the Patent Act 1977, has been repealed by section 70 of the Competition Act 1998 apparently to bring national law in line with EU antitrust laws.[95] Although section 44 concerned only enforceability of licensing agreements, this preference for

88 Following the logic that you can only abuse a right that already exists: Temmerman (n 88), p 11.

89 Availability of damages for abusive enforcement would not help the generic producers in the *AstraZeneca* case, since no patent enforcement has occurred there. This makes the timing of the abuse as defined in the antitrust context crucial.

90 See Daryl Lim, *Patent Misuse and Antitrust Law:Empirical, Doctrinal and Policy Perspectives* (Edward Edgar 2013).

91 *Princo Corp v International Trade Commission* 616 F.3d 1318 (Fed. Cir. 2010), 1328-1331.

92 Lim (n 90), pp 2-3.

93 See Christopher A Cotropia, "Modernising Patent Law's Inequitable Conduct Doctrine" (2009) 24(2) Berkley Technology Law Journal 723 (noting how the doctrine can act to improve patent quality); Kevin Mack, "Reforming Inequitable Conduct to Improve Patent Quality: Cleaning Unclean Hands" (2006) 21 Berkley Technology Law Journal 147 (noting the inability and unwillingness of the Patent Office to investigate claims of inequitable conduct).

94 See *Aventis Pharma v Amphastar Pharm*, 2007-1280 (Fed. Cir. 2008) (requiring an intent to deceive).

95 James B. Kobak, *Intellectual Property Misuse: Licensing and Litigation* (ABA 2000), p 151.

solving the issues of abuse through competition law rather than patent law[96] is telling of the general trend occurring in the EU as a reaction to antitrust involvement.

57. Defensive mechanisms available in the event of a patent infringement action rely on the involvement of private parties (which is reflective of the functioning of the whole patent system which relies on private parties to challenge patents) in circumstances where there might be an expectation of a state-driven redress. Relying on defensive mechanisms also moves the problem to the post-grant stage in which the patent offices can no longer intervene. The argument that a patent litigation remedy is available (if at all) too late,[97] however, is equally applicable to antitrust enforcement which usually happens years after the event. Only a more active role of the patent offices could ensure that attempts of abuse are weeded out at an early stage. Alternatively, an availability of a private action in damages that could be used a 'sword' or an extension of the grounds on which opposition proceedings can be pursued could be of use, if it is considered that limitations on the resources of the patent authorities deem reliance on public enforcement impossible.

58. In so far as reliance on general concepts of abuse in the patent context might be underdeveloped and no damages can be obtained, existing restrictions on patent enforceability can constitute an inadequate deterrent for the patent holders. At the same time, the deterring effect on the generic producers' willingness to enter the market might have already occurred, as pointed out in the *AstraZeneca* case. This would seem to confirm that antitrust involvement comes in as a reaction to the failure of the patent regulatory system in tackling instances of abuse on its own. The effect of antitrust involvement might be to slow down the evolution of patent law remedies. It might allow, however, for an availability of a competition defence in patent infringement cases that could act akin to equitable defences discussed above.

VII Conclusions

59. The Court of Justice decision in *AstraZeneca* has shown that it is not just the outcome that matters. Although the outcome of that particular case could be described as pro-innovation, the deconstruction of the arguments in that case reveals a very different picture. It reveals a picture of unsubstantiated distrust towards the patent system,

96 Lionel Bently and Brad Sherman, *Intellectual Property Law* (OUP 2014, 4th edn), pp 647-648.
97 Temmerman (n 88), p 37.

which exposes a risk of a biased approach. It shows that innovation might not have played the primary role in the deliberation process and that instead the authorities preferred to focus on the goal of facilitating generic entry with a view to lowering of the prices, thus confining antitrust to a limited role. At the same time, the policy issues at the intersection between competition and patent policies have been almost wholly sidestepped to the detriment of innovation.

60. Without doubts the question of abuse of the patent application process constitutes a difficult regulatory problem, but it is not even clear whether competition law involvement is the best solution to it. At the same time, it is clear that patent law or general law solutions to the problem are underdeveloped or non-existent. Even if one accepts that competition involvement is warranted, above all because of the failure of the patent system to address the issue itself, then that should be conditioned upon a greater sensibility of competition authorities towards the wider policy issues at play if innovation is not to suffer. Yet, so far the authorities failed to openly approach the issue or to attempt a proper balancing exercise of the sometimes diverging interests. The expectation that a more interventionist approach of the competition authorities would be matched by a more in-depth involvement in questions of patent policy in so far as they shape the conditions of competition has not materialised. What seems to be lacking is a realisation that each regulatory choice taken by the competition authorities regarding the competition-patent intersection carries with it a need to adapt its deliberation process.

61. Failure to delineate the limits of antitrust intervention in *AstraZeneca* opened the doors to speculation and thus created uncertainty for the patent holders as to the reward value of patents. This is significant from the innovation perspective for it might affect the incentives to innovate. Italian *Pfizer* case is just an illustration of how significant the problem might be. It is also an example of a seriously deficient reasoning and as such a representation of what the European approach should try to avoid to become. It also demonstrates the risks and challenges created by the deficient reasoning underlying *AstraZeneca*. To the extent that uncertainty is inherent in antitrust involvement, it serves to illustrate the drawbacks of a case-by-case approach followed by that field of law.

62. Although on the face of it the potential for conflict between competition and patent policy was not as clearly visible in *AstraZeneca* as in the case of reverse payment settlements, the way the issue was played out by the authorities made it a real

possibility. The highly subjective competition of the merits approach as epitomised in *Pfizer* allows for a very interventionist approach that is based on separate treatment of competition and patent policies. The way the role of competition and patent law as well as their interaction is portrayed by the authorities is significant for it shapes the format for discussion of the innovation angle. The cases analysed in this chapter show that the competition on the merits approach is not conducive to a fruitful discussion of the innovation dimension in so far as it relates to the relationship between antitrust and patent law.

63. The deficiencies in the approach of the competition authorities to the issues at the competition-patent intersection identified in this chapter should be borne in mind for the discussion of the ways to improve the European approach to be had in Part III.

Chapter 5

Pharmaceutical Sector Inquiry – a useful exercise?

I Introduction

1. From the last two chapters it should become evident that the Pharmaceutical Sector Inquiry[1] conducted by the European Commission constituted an important background to the investigations discussed there. As such the Final Report from that inquiry has already been referred to in those two chapters in connection to the abusive conduct discussed therein. However, together with other documents produced as part of the inquiry, it is also an important official document that may shed some further light on the question of how the Commission builds an approach to the antitrust-patent interaction and so it deserves some further attention.
2. Since the pharmaceutical industry is knowledge and R&D based, a significant part of the inquiry related to the use of patents in that industry. Accordingly, the Report from that inquiry constitutes an important insight into the DG Competition's approach to patents, as discussed in section IV of this chapter. It will be seen, however, that the Report hardly touches on the question of management of the patent-antitrust relationship and its treatment of the innovation dimension is not entirely satisfactory. The scope of the inquiry, including the treatment of the innovation dimension, is discussed in section II. A discussion of the purpose of the inquiry is in fact a theme that runs throughout this chapter. The question of purpose is linked, in turn, to the question of usefulness of that exercise as a policy or a strategy instrument. This in part relies on the pertinence of the findings (section III). The analysis of the document shows that it might have had a misguided focus as well as that some of its findings might have been misplaced, in particular in respect of an approach to patents which shows signs of a potential for bias. The chapter also discusses the Sector Inquiry as a "conversation in the making" between different regulatory bodies (section V). In connection to that it considers the input from the stakeholders that was provided during the public consultation in so far as it relates to the question of the interrelationship between patent and antitrust policies and the discussion of the

[1] European Commission, "Pharmaceutical Sector Inquiry: Final Report" (8 July 2009); European Commission Press Release IP/08/49 of 16 January 2008: "Antitrust: Commission launches sector inquiry into pharmaceuticals with unannounced inspections".

purpose of the inquiry (section V). This aspect of the sector inquiry is significant from the perspective of eventual signalling developing between antitrust and patent authorities. Finally, the chapter concludes with an attempt to position the Sector Inquiry within a wider context (section VI).

II The purpose of inquiry

An information gathering exercise

3. The Commission's power to conduct sector inquiries into particular sectors of the economy or into particular types of agreements across various sectors stems from article 17 of the Regulation 1/2003 EC.[2] Both the positioning of the power within that antitrust Regulation as one of the powers of investigation and the specific article establishing the power make it clear that inquiries are to be conducted where there are suggestions that competition may be restricted or distorted. This sets the context within which inquiries are being held, but it does not specify the exact purpose of those inquiries. Equipped with an ability to request information and conduct down raids,[3] the Pharmaceutical Sector Inquiry has turned into an extensive information gathering exercise, which was immediately followed by several investigations (including the ones against Lundbeck and Servier discussed in chapter 3).

4. The pharmaceutical sector inquiry is one of the eight sector inquiries conducted by the Commission to date and is by far the most extensive one, at least in terms of the length of the Report that it led to. In fact, looking at the width of issues that it treated, only the e-commerce inquiry might equal its extent.[4] Taking previous sector inquiries as a reference point, they were all conducted to help the Commission to assess whether it needs to open competition investigations. As conducting a sector inquiry might have the effect of putting an industry in the spotlight,[5] these investigative powers might have an effect of pressuring firms into changing their behaviour. For example, the sector inquiry into leased lines (telecoms) was dropped after a significant drop in the

2 Council Regulation (EC) No 1/2003 of 16 December 2002 on the implementation of the rules on competition laid down in Articles 81 and 82 of the Treaty, [2003]OJ L 1/1.

3 Pharmaceutical Sector Inquiry was the first Sector Inquiry to make use of down raids, which were conducted as the launch of the Inquiry was announced.

4 European Commission Press Release IP/15/4921 of 6 May 2015, "Antitrust: Commission launches e-commerce sector inquiry".

5 However, it also allows for discussing the issues outside the spotlight of enforcement: Thomas Kramler (Head of the Digital Single Market Task Force, DG Competition), "The European Commission's E-commerce Sector Inquiry" (2017) 8(2) Journal of European Competition Law & Practice 81, 82.

prices occurred while the inquiry was ongoing.[6] The pharmaceutical sector inquiry broadly followed the steps of the other inquiries in terms of aims it was meant to achieve.

5. The press release announcing the launch of the pharmaceutical inquiry stated that the inquiry was initiated in response to indications that fewer new pharmaceuticals were brought to the market and generic pharmaceuticals' entries were delayed.[7] The purpose of the inquiry was thus to gain an understanding of why this was happening. Yet, the press release also declared that the aim of the inquiry was to examine whether the practices pursued by the pharmaceutical companies may infringe on article 101 or 102. This announcement raised expectations that the Report which was to arise out of the inquiry would contain some guidance as to which practices might be considered problematic from the antitrust perspective – a timely issue following the Commission decision in *AstraZeneca*.

6. That expectation, however, did not come to fruition. The Commission's Report proved to be largely limited to a fact-finding inquiry analysing company behaviour and the underlying regulatory framework without providing any guidance on the compatibility of the identified practices with EU antitrust law. Indeed, the Commission was at pains throughout the Report to emphasise that it is not meant to provide any guidance in that respect, but only to provide the Commission "with relevant context and a factual basis for deciding whether and what further action is needed".[8] In this respect, this sector inquiry might be said to be coming short of the financial services inquiry which openly identified some competition concerns following the investigation into retail banking.[9]

7. Admittedly, the fact-finding analysis performed as part of the inquiry in itself was an enormous task, which was accomplished in a relatively short time (18 months from the launch of the inquiry to the final report with a public consultation on the preliminary

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6 European Commission Press Release IP/99/786 of 22 October 1999 "Commission launches first phase of sectoral inquiry into telecommunications: leased line tariffs"; European Commission Press Release IP/02/1852 of 11 December 2002 "Price decreases of up to 40% lead Commission to close telecom leased line inquiry"; the investigation predated Regulation 1/2003 and was conducted under art 12 of Regulation No. 17/62 of 21 Feb 1962, OJ 13/204.

7 European Commission Press Release IP/08/49 of 16 January 2008: "Antitrust: Commission launches sector inquiry into pharmaceuticals with unannounced inspections".

8 Para 22 of the Final Report.

9 European Commission Press Release IP/07/114 of 31 January 2007, "Competition: Commission sector inquiry finds major competition barriers in retail banking"; Communication from the Commission, Sector Inquiry under Article 17 of Regulation (EC) No 1/2003 on retail banking (Final Report) COM(2007) 33 final.

report conducted during that time), especially considering the limited resources of DG Competition. The inquiry allowed it to gather a lot of information about the trends and the functioning of the industry, in particular in respect of patent practices. Yet, it is still disappointing that the Report did not form a basis for a wider policy discussion. In that sense it could be considered a missed opportunity, even if previous experience of sector inquiries did not lend itself to such expectation. Unlike previous sector inquiries, the Pharmaceutical sector inquiry touched upon practices which could constitute novel forms of abuse, strengthening the need for their consideration from a competition law perspective.

8. The unfortunate outcome of the limited stated purpose of the inquiry was that it introduced a considerable level of uncertainty on the part of the originator pharmaceutical producers. This is because the investigations and the ensuing prohibition decisions concerning reverse payment settlements that immediately followed the Report suggested that the Commission considers at least some of the practices identified in the Report as anticompetitive, reverse payment settlements being one of the practices discussed there. This, coupled with the general tone of the Report, raised doubts as to antitrust compatibility of other practices named there. Since this uncertainty pertains to the question of the strength of patents as rewarding mechanisms, it has a direct bearing on the innovation dimension and it is thus of considerable importance. While it could be argued that the Sector Inquiry Report was just a first step in the Commission's response to the perceived problems in the industry and that the situation could be clarified afterwards, nine years after the Report it appears that the issue is not much clearer than it was then.

Focus on delay of generic entry

9. As already stated above, the object of the sector inquiry analysis was an examination of the reasons behind the apparent decline of innovation in that sector as well as delays of generic entry. The Report, however, clearly concentrates on the latter issue. This is acknowledged already at the outset of the Report which outright states that the inquiry focused on obstacles to generic entry.[10] The selection of INNs[11] for the analysis was

[10] Para 3.
[11] International Non-Proprietary Name for pharmaceutical substances.

also made with the originator-generic producer relationship in mind.[12] The Report likewise openly acknowledges that the inquiry did not analyse factors, such as uncertainty about financial rewards, which could contribute to the decline of innovation in the sector apart from company behaviour.[13] This constitutes a major shortcoming of the Report and the inquiry. It suggests that its results can be one-sided, leading to a supposition that any policy based on those findings could be biased. Although the press release accompanying the publication of the Final Report claimed that further market monitoring would follow to identify the factors that contribute to the decline of innovation as observed in the Report,[14] no further reporting on that front has occurred since.[15]

10. Still, the other object of the inquiry, the delay of generic entry, could be considered significant also from the innovation perspective, since generic competition "creates and maintains incentives for innovation"[16] by putting pressure on the originators to continue searching for new innovations and because generic producers can equally be involved in the innovative process by developing new formulations or methods of delivery.[17] This aspect of the damaging impact of delay of generic entry was indeed acknowledged by the Commission in its Report. However, the Commission's interest in the delay of generic entry was predominantly triggered by the fact that generic entries bring about decreases in prices. This much is clear not only from the Report, but also from the press release, which puts a much greater emphasis on the price effects of the delay of generic entry and mentions the innovation aspect only in passing. Moreover, when discussing the consumer welfare effects of delayed generic entry, the Report equates it to a delay in price reductions.[18]

11. Does that mean that the Commission missed the boat with the Pharmaceutical Sector Inquiry? To an extent, yes. Certainly, numbers like a loss of € 3 billion speak to the imagination and indeed unduly high prices could constitute a significant source of

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12 See para 1146 of the Final Report, summary at the end of section 3.2, or p 16 of the Executive Summary of the Report.

13 Para 21.

14 European Commission Press Release IP/09/1098 of 8th July 2009, "Antitrust: shortcomings in pharmaceutical sector require further action".

15 The only reports that followed the Sector Inquiry Report were annual Monitoring Reports concerning patent settlements.

16 Final Report, para 92.

17 Final Report, para 93.

18 Paras 1076-1079; "A proxy for the *overall* damage suffered by consumers can, at constant consumption volumes, be calculated by multiplying (a) the difference between the actual and the expected price and (b) the quantities traded during the period of delay" (para 1079, emphasis added).

consumer harm,[19] particularly in the area of health in which access to affordable medicines constitutes an issue that inspires strong reactions. Yet, this emphasis on consumer harm understood in the narrow sense takes the attention away from issues that might be far more important. Even if one concentrates on the social welfare aspect of access to medicines, it is not just about them being affordable, but also effective, the latter feature depending largely on the level of innovation within the pharmaceutical sector. It is not enough to acknowledge that delays of generic entry can be also damaging to innovation. An examination of a knowledge-based, patent intensive industry like the pharmaceutical industry should be framed in innovation terms just as much as it is framed in the short term costs for it influences the way in which cases are later considered (as evidenced by the treatment of reverse payment settlements). Yet, it seems that although the Report recognises the key role played by innovation in the pharmaceutical sector,[20] the inquiry failed to fully embrace that aspect in its analysis. This is so despite the fact that some of the respondents to the consultation pointed out that this is a vital aspect to be considered. From among them, a strong voice in favour of a treatment focused on innovation came from Justice Jacob, who warned that the approach taken by the Commission in the Report might lead to savings today at the expense of fewer future medicines.[21]

12. One reason for this apparent imbalance of treatment might be that factors that affect innovation are beyond the reach of competition analysis which is focused on the conduct of companies.[22] Yet, although sector inquiries are tools of competition law, the pharmaceutical sector inquiry managed to consider also a number of regulatory matters arguably going beyond the reach of competition policy in the strict sense, but nonetheless constituting a vital element in understanding the way in which the pharmaceutical industry functions.[23] In those circumstances, consideration of factors affecting the rate of innovation would not seem to be that farfetched. Innovation would also need to come to the fore as a relevant feature of the inquiry to a greater

19 This estimation of losses due to delay of generic entry was announced together with the Preliminary Report, see European Commission Press Release IP/08/1829 of 28th November 2008, "Antitrust: preliminary report on pharmaceutical sector inquiry highlights cost of pharma companies' delaying tactics".

20 See para 8 of the Final Report.

21 A contribution from The Rt. Hon. Sir Robin Jacob was not one of the formal submissions to the public consultation, but was given during one of the public presentations on the Preliminary Report organised by the Commission, available at http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/jacob.pdf (accessed 5th April 2016).

22 See para 15 of the Final Report.

23 On that point see further below, paras 27 ff.

extent if the question of incentives of the originators and the generic producers were examined in more detail.[24]

III A critique of the findings

13. The above suggested that the Pharmaceutical Sector Inquiry Report might have had a misguided focus. It might also be that it showed some misguided understanding of the sector. The report could be criticised not solely for the fact that it did not take the opportunity to discuss antitrust policy issues arising in respect of the practices it analysed. It was also heavily criticised, in particular by the originator companies, for arguably having reached misplaced conclusions by unjustifiably establishing a causal link between patent strategies it discusses and delay of generic entry.[25] In that respect, the Final Report conclusions are, however, much more cautious than the Preliminary Report findings.[26] Although it claims that the sector inquiry showed that "company practices are among the causes" of delay of generic entry, it also states that it "suggests that a variety of other conditions might play also an important role."[27] Still, a careful look into the data collected as part of the inquiry could call into question even the correlation between the two.

14. Firstly, in the area where the delaying tactics or strategies are supposed to be the most widespread, i.e. in relation to top-selling medicines, the delay in generic entry has been shown to be actually shorter (weighted average of 4 months from patent protection expiry compared to 7 months in general[28]). Secondly, although the use of patenting strategies is said to have increased, the speed with which generic products reach the market also appears to have increased.[29] Overall, the report lacks a

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24 To that effect Gylesen criticises the Report for concentrating on the foreclosure effects, without considering the issue of possible justifications: Luc Gylesen, "The EC Sector inquiry into Pharmaceuticals, Quo Vadis, Commission?" (2009) Feb(2) Global Competition Policy, p 8.

25 James Killick and Anthony Dawes, "The Undetected Elephant in the Room: An Analysis of DG Competition's Preliminary Report on the Pharmaceutical Sector Inquiry" (2009) Feb(2) Global Competition Policy.

26 See the European Commission Press Release IP/08/1829 of 28th November 2008, "Antitrust: preliminary report on pharmaceutical sector inquiry highlights cost of pharma companies' delaying tactics" which speaks of causation in unequivocal terms.

27 Para 1607 of the Final Report.

28 Pharmaceutical Sector Inquiry, Preliminary Report Fact Sheet "Prices, time to generic entry and consumer savings", p 2.

29 Para 195 of the Final Report.

regression analysis that would unequivocally show an impact of the "tool-box of strategies" on generic entry.[30]

15. Equally, the Report could be criticised for the method with which it measures the rate of innovation, which is using the proxy of a number of novel medicines reaching the market. The problem with this method is that it obviously disregards incremental innovation. It is also unclear how to square the conclusions about the decline of innovation in the sector based on that method, with a finding that the amounts invested by the originator companies in R&D have increased, at least in absolute terms. Could this suggest that the problem does not lie with the incentives to innovate, but rather a decreased success rate in discovering new medicines? All in all, originator companies have pointed out to the Commission the increased scientific complexities as one of the factors affecting the rate of innovation.[31] Yet, it could be also that R&D spending itself is a weak proxy for the rate of innovation – increasing costs of clinical trials (that take up a significant proportion of overall R&D costs)[32] could suggest that the increasing amount of money spent on R&D does not necessarily correspond to the amount of innovative activity.[33]

IV Approach to patents

16. Since the pharmaceutical sector is one that heavily relies on patents, the Sector Inquiry Report understandably devotes significant attention to the patent system. Yet, it might be another way in which the Report displayed a misguided understanding of the sector as it might have made some unwarranted assessments about use of patents, at least implicitly. The Report contains a whole section dedicated to explaining the regulatory framework for patents in Europe.[34] It also contains the standard exposition of the rationale behind patents, in which it highlights the innovation function of patents. Notably, this account takes note also of the competition-enhancing role of patents[35] – a feature which is often overlooked in competition analysis – which is a positive development, moving away from a simplified understanding of patents as grants of a

30 Bill Batchelor, "EC tones down its final report into the pharma sector, but ramps up enforcement activity" (2010) 31(1) European Competition Law Review 16, p 17.
31 Para 21 of the Final Report.
32 Para 1523 of the Final Report.
33 Coincidentally, the higher the cost of investing in R&D, the greater the risk taken, thus the greater importance of rewards obtained from patent exclusivity.
34 See section 2.1 of Part B.
35 Para 255 of the Final Report.

monopoly power, that shows a well-rounded understanding of the way patents work. The Report further recognises the particular importance of patents in the pharmaceutical sector stemming from the high costs and high risks associated with investing in innovation in that sector.[36] In line with the general emphasis on delays on generic entry, the section also notes that time limits put on patents also stimulate innovation.

17. The main part of the Report concentrates on patent strategies employed by the originator producers. According to the Commission, originator companies employ a "tool-box" of strategies that may contribute to delaying or blocking generic entry. The use of that terminology has met with a strong criticism following the publication of the Preliminary Report, since it was taken as suggesting that the practices described as part of those "tool-box" of strategies are anticompetitive while it was argued by some of the stakeholders that these practices are completely legitimate.[37] The Commission countered that it did not intend to judge the patent strategies, but merely analyse which of them exist, what might be their objective, and whether they have any specific effect.[38] Still, the same "strategy" language can be found in the *Servier* and *AstraZeneca* decisions,[39] which could suggest that the use of that wording in the Report was not altogether neutral.

18. In a similar vein, the Commission did not consider the use of the terms such as "secondary patents", "patent thickets" or "defensive patenting" to be pejorative. While such terminology has no official place in patent law, the Commission considered that those terms are widely used in the industry and are meant to be merely descriptive of certain practices employed by the patent holders.[40] To take an example of secondary patents, according to the Commission Report, the term should be understood to denote patents that follow the primary patents as viewed purely from a time perspective and not to imply that those patents are of a lower value or quality. Yet, the use of this terminology coincides with an accusation made by some of the generic producers to that effect. The Commission was also clearly testing this claim when it examined the patent challenge success rates separately for secondary and primary patents.

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36 The Report estimates that the cost of bringing a new medicine into the market might oscillate anything between US$ 800 million and US$1 billion (para 149, the cost includes unsuccessful trials) with only 1 in 5,000-10,000 compounds tested being successfully launched (para 161, relying on data from EFPIA).

37 Para 1509 of the Final Report.

38 ibid.

39 Case AT.39612 *Perindopril (Servier)* of 9 July 2014, C(2014) 4955 final, e.g. para 2960 ("overall strategy"), Case COMP/A.37.507/F3–*AstraZeneca* of 15 June 2005, eg. para 860.

40 Para 20 of the Final Report.

Moreover, among its recommendations it listed the need to ensure that only deserving applications are granted patent protection,[41] further suggesting that it might see a problem in that area.[42]

19. The problem of negative connotations that are associated with the use of a particular terminology would not have been so significant had the Commission openly discussed those underlying assessment issues. The importance ascribed to the use of terminology is a direct consequence of leaving the market players with raw data not accompanied by sufficient commentary, which opened the doors to speculation. In fact, the Commission acknowledged in this very context that some of the stakeholders regretted that the Preliminary Report did not provide competition guidance.[43] Despite numerous disclaimers that can be found throughout the Report, it was inevitable that in absence of guidance the stakeholders would try to read between the lines and form a view based on the general tone of the Report. And indeed, the overall tone of the Report appears to be negative towards the way the patent system is used by the originator companies. This is so, despite the fact that the Final Report is a significant tone down from the language used in the Preliminary Report.[44] This trend, however, might be reminiscent of other sector inquiry reports.

V A conversation in the making

20. While the implicit aim of the sector inquiry was to assess anticompetitive risks, the Report is not limited to the analysis of undertakings' behaviour. Some of the criticisms that can be found in the Report relate to the way the patent system works, regardless of any strategies that the patent holders might use. This is visible, for example, in respect of the opposition proceedings before the EPO,[45] which were criticised in the Report for taking too long (on average 3,6 years).[46] Correspondingly, in the Preliminary Report the Commission expressed an opinion that the EPO should raise its standards for the detection of abuses of voluntary divisional applications – a suggestion that in the meantime was actually addressed by the EPO, which adopted measures to limit the

41 Thus suggesting that sometimes patents are granted in respect of applications which are not "solid" and/or bring about insufficient inventive contribution.
42 Para 1324 of the Final Report.
43 Para 1509 of the Final Report.
44 Catriona Hatton, Suzanne Rab, Jean-Michel Coumes and David Cardwell, "European Commission pharmaceutical sector inquiry final report - drug problems remain but Commission backs down" (2009) 20(11) International Company and Commercial Law Review 375.
45 European Patent Office.
46 Para 1339.

time in which a divisional application can be made. In a similar vein, the Report made recommendations for the creation of a Community patent and a unified patent litigation system, seeing that bundles of national rights translate to significant litigation costs and numerous parallel proceedings that contribute to the delays of generic entry and general inefficiency of the system. The Report links those recommendations to the benefits for innovation and competition which would be thus stimulated, yet this focus on the patent side of the matter is interesting, because it calls for a course of action that is outside the realm of antitrust to solve the perceived problems.

21. In this way, the Commission could be said to be opening a conversation with patent authorities and other regulatory bodies. The Commission was prepared to engage in the discussion of possible regulatory solutions, for example by discussing, but ultimately not recommending, "clearing the way" mechanism before launch of a generic entry whereby the originator would be notified of an application for a marketing authorisation by a generic company with a view to having a possibility of bringing patent infringement proceedings.[47] In that sense, the Commission could be said to be taking a wide view of the purpose of the Sector Inquiry. This could be taken as a positive sign, since it marks a more interdisciplinary approach. Indeed, the EPO was actively involved in helping the inquiry, with an expert seconded to the Commission.[48] The Pharmaceutical Sector Inquiry Report is not the first to take a more integrative approach, for example the Financial Sector Inquiry suggested that come of the competitive barriers it identified might be solved through the introduction of SEPA.[49] Such wide-encompassing view of the issues at play is in fact necessary, if one wants to see whether antitrust involvement is warranted.

Public consultation

22. Yet, the indications of a willingness to take a more interdisciplinary approach were perhaps not taken to their full. While the Preliminary Report was based on information gathered through requests for information and during the down raids, the Sector

47 Para 1352 ff of the Final Report; patent linkage (i.e. "the practice of linking the granting of MA, the pricing and reimbursement status or any regulatory approval for a generic medicinal product, to the status of a patent (application) for the originator reference product" (para 336)) is not allowed in the EU.

48 Theon van Dijk, "On possible cooperation between patent offices, competition authorities and SSOs", OECD Competition Committee Hearing on Standards Setting Paris, 17 December 2014, available at http://www.slideshare.net/OECD-DAF/ip-standard-settingtheonvandijk17dec2014 (accessed 20 January 2017), slide 3.

49 Single Euro Payments Area; Communication from the Commission (n 9), para 45.

Inquiry also constituted a perfect opportunity to gain views from a wide variety of stakeholders, since it was subject to a public consultation.[50] 75 formal contributions were submitted, which represented a wide variety of views. Notable among them was the interest of intellectual property associations and lawyers, which was not limited to European bodies, but also included responses from associations like AIPLA (American Intellectual Property Law Association) [51].

23. These bodies were unanimously critical of the Preliminary Report. Apart from submitting observations concerning the assessment of particular practices named in the Report, they were critical of the negative attitude to patents emanating from the Report. The UK's Intellectual Property Institute[52] put into question the impartiality of the Report, because of the negative, one-sided way in which it was presented, claiming also that some of the data analyses were skewed to fit preconceived theories. IP Federation[53] condoned the hostile attitude towards the innovators and expressed concern over the fact that the Report showed little indication that it was aimed to encourage innovative, research based companies. While some of the IP associations involved in the consultation were representing patent holders, making their criticism of the Report unsurprising, their responses still constituted an invitation to consider the patent side of the issues in more depth (if only to avoid a risk of bias) and a signal that the Commission's approach might have an impact on patent interests.

24. Furthermore, many of the responses noted that the Sector Inquiry Report raised general matters of patent law going beyond the pharmaceutical industry and as such required a more general discussion as a matter of patent policy. IPLA (Intellectual Property Lawyers' Association)[54] observed that the DG Competition consulted on issues of patent law with the EPO, other Commission Directorates, EFPIA (European Federation of Pharmaceutical Industries and Associations)[55] and the European Generic Association, this being the first occasion on which it had an opportunity to examine in detail how the patent system works. While IPLA was anxious that the Commission might not be aware that many of the practices which cause its concern, such as

50 Art 17 of Regulation 1/2003 EC expressly provides for such possibility.
51 A national bar association representing both patent owners and patent users.
52 Dedicated to helping intellectual property owners.
53 UK IP industry trade association.
54 An association of UK IP solicitors.
55 Representing pharmaceutical companies involved in R&D.

divisional patents,[56] are inherent in the patent system, it noted the need for patent practitioners to be learned in competition law, since those issues arise and need to be considered in the course of patent proceedings. All of the above could be suggestive of the need to cooperate between antitrust and IP bodies.

25. While the fact that the Commission consulted on patent matters with bodies like the EPO is of course a positive sign, it appears that the opportunity offered by the public consultation was not fully used. The press release accompanying the Final Report stated that the inquiry has contributed to the debate on the European policy on pharmaceuticals.[57] Yet, this debate in so far as it relates to the interaction between patents and antitrust is not visible in the Report. To the contrary, it seems that the strongly critical voice of the intellectual property bodies has not been taken on board. While these responses raised some interesting policy issues concerning the interaction of antitrust and patent policies,[58] the heightened interest in those issues raised by the public consultation seemingly has not translated to a deepened discussion of those by the Commission, at least not in the Report.

26. The Report refers to the relationship between competition law and industrial property law only in short,[59] mentioning the coinciding aims of the two bodies of law in promoting innovation but without going into the details on how this relationship should be managed in practice. It only states that existence and exercise of industrial property rights as such are not of themselves incompatible with competition law, but they are not immune from competition scrutiny in exceptional circumstances. Despite those assurances, the tone of the Report raised questions as to whether the Commission intended to modify the balance between competition law and intellectual property rights.[60]

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56 By way of comparison it noted that the US Patent and Trademark Office allows for a much more extensive use of divisional patents.

57 European Commission Press Release IP/09/1098 of 8th July 2009: "Antitrust: shortcomings in pharmaceutical sector require further action".

58 For example, the EPO pointed out to the discomfort of classifying practices according to intent, this concept being foreign to patent law.

59 See para 1568 of the Final Report and para 13 of the Annex (mentioning *AstraZeneca* as an example of antitrust intervention in IP matters).

60 Kristina Nordlander and Steve Spinks, "The Interplay of Patenting Strategies and Competition Law in the Pharmaceutical Sector Inquiry" (2009) Feb(2) Global Competition Policy, p 7, noting also that application of antitrust to defensive patenting or patent clusters would call into question the very existence of patent rights (p 8).

VI Wider picture - where next?

27. While the Pharmaceutical Sector Inquiry was a competition inquiry led by DG Competition, the Report's recommendations concern mostly regulatory matters outside the remit of competition law. Apart from the recommendations concerning the functioning of the patent system, the Report recommended streamlining of the marketing authorisation process and improving pricing and reimbursement systems. All of these issues of course affect the conditions of competition within the market, but the explicitness of recommendations for other branches of the law might still be considered surprising when compared with the non-specific course of action proposed for antitrust and bearing in mind that it was an antitrust inquiry. This further reinforces a view that the sector inquiry report was a form of conversation between regulatory bodies. The EPO's response to the Commission's criticisms concerning that body's functioning would suggest that these non-antitrust recommendations proved to be influential, in so far as it claimed that they bolstered its own "raising the bar" initiatives. At the time of the Sector Inquiry the process of creation of a Community patent was already underway, so in that sense the Sector Inquiry's findings could be said to be further reinforcing that initiative. As for the other recommendations, a further inquiry would be required to see how much has changed in the national reimbursement systems. One notable policy development at the European level in this area that was triggered by the inquiry was a revision of the Transparency Directive to shorten the times in which pricing and reimbursement decisions are made.[61]

28. Furthermore, in the Report the Commission pledged an intensification of competition law scrutiny, since it considered that the inquiry identified a number of issues that warranted further investigation. It stated that it would not be hesitant to use its enforcement powers and indeed several enforcement actions followed soon after. Thus, it was apparent that at that point the Commission had already formed a view on the compatibility with the EU competition law of at least some of the practices discussed in the Report. In fact, the Report already contains hints to that effect in respect of reverse payment settlements (not limited to the announcement of the further

[61] Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems (1989) OJ L 40; see European Commission Press Release IP/12/205 of 1st March 2012 , "Commission proposes faster access to medicines for patients".

monitoring reports into patent settlements).[62] Thus, the approach of the Commission was to jump from a fact-finding inquiry straight to intensive enforcement.[63] While nobody questions the ability of the Commission to enforce antitrust infringements at any point in time, in terms of an evolution of a policy approach some doubts might be expressed as to desirability of such pathway. This is especially so, since some of the respondents to the public consultation raised strong arguments suggesting that the Report could not form a reliable basis for a future strategy.[64] In effect, the Commission relinquished an opportunity for an open-ended discussion of a theory of harm outside the prosecution context at a time when the stakeholders were clearly prepared to offer their input on the point.

29. It could be argued, however, that at the end of the day the only way to form a competition policy in the area is to rely on case law development based on concrete examples. As with every case law development, this approach has its advantages and disadvantages. Such an evolutionary step-by-step approach allows for the arguments to crystallise in individual cases as brought to the attention of the Commission by the parties and dispels the need to formulate general statements in the abstract (which could be a drain on the resources), but at the same time policy development risks being aimless and prone to considerable uncertainty especially at the early stages of the development (as is the case here). What input the Sector Inquiry provided in that context is not clear, since it is questioned whether it could have provided a good sense of direction for the enforcement activity.

30. In the circumstances, it becomes probable though, that it will take many years before (if at all) the Commission decides to provide more extensive guidance on the approach to the patent-antitrust intersection similar to the policy documents produced by the FTC or in other major jurisdictions.[65] Query if the research-based industries will not suffer from the wait. Public consultation on the Preliminary Report strongly suggested that pharmaceutical companies would welcome guidance in this very complex area.

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62 Para 1573 of the Final Report: "Agreements that are designed to keep competitors out of the market may also run afoul of EC competition law. Settlement agreements that limit generic entry and include a value transfer from an originator company to one or more generic companies are an example of such potentially anticompetitive agreements...".

63 Similarly the e-commerce sector inquiry appears to have served as a springboard to competition enforcement: European Commission Press Release IP/17/201 of 2 February 2017 "Antitrust: Commission opens three investigations into suspected anticompetitive practices in e-commerce".

64 See, for example, IP Federation's contribution, p 4.

65 Federal Trade Commission, "To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy" (October 2003); see further ch 10 for the discussion of the US policy documents in the area. Canada, South Korea, Japan and India all have published antitrust guidance on IPR.

Similarly, commentators warned of an unhealthy level of uncertainty that the Report might create.[66] As a consequence of the legal uncertainty created by the Report companies might abstain from practices which are perfectly legal, thus undermining the value of their patent rights, ultimately leading to a chilling effect on innovation. A somewhat ironic result, considering that innovation was something the DG Competition strives to encourage.

31. It might be that in the circumstances litigation simply cannot replace guidance "in providing a coherent legal framework."[67] Still, it should be acknowledged that there exist other outlets for policy creation – although not providing official guidance and thus certainty to the undertakings, antitrust policy might also develop through external forums, in which the European Commission also participates, such as OECD roundtables series.[68] In that respect, it should be noted that the purpose of the sector inquiries conducted by the Commission is rather limited and one should not expect too much from them. Instead, the pharmaceutical sector inquiry should be taken as just one step within a multitude of other Commission strategies and initiatives undertaken by the Commission,[69] including those mentioned at the outset of the Report, i.e. the Commission's Industrial Property Rights Strategy,[70] Enhancing of Patent Rights,[71] the Communication on the Renewed Vision of the Pharmaceutical Sector,[72] Innovative Medicines Initiative,[73] or the Lisbon Strategy more generally. In that respect, the fragmentation of EU institutions in dealing with various regulatory matters poses a challenge when an issue requires a cross-sectional approach. It raises issues about cooperation between different Commission Directorates and also with other national or European bodies, in particular on the IP side.

66 See, e.g. David W Hull, "DG Competition's Preliminary Report on the Pharma Sector Inquiry: A Need for Clear Signals at the IP/Competition Intersection" (2009) Feb(2) Global Competition Policy, p 3.

67 ibid, p 9.

68 See ch 10 for a discussion of the work done by the OECD in this area.

69 This is not unique for this sector inquiry. Other sector inquiries were also conducted as part of larger Commission schemes, such as the e-commerce inquiry which is part of the Digital Single Strategy or the Energy inquiry into capacity mechanisms that complemented Commission's Energy Union Strategy.

70 European Commission Communication of 16 July 2008 on an Industrial Property Rights Strategy for Europe, COM(2008)465 final.

71 European Commission Communication of 3rd April 2007 Enhancing the Patent System in Europe, COM(2007)165 final.

72 European Commission Communication of 10 December 2008 Safe, Innovative and Accessible Medicines: A Renewed Vision for the Pharmaceutical Sector, COM(2008)666.

73 See http://www.imi.europa.eu/. IMI is a joint public-private initiative between the European Commission and EFPIA aimed increasing the speed of development of new medicines.

VII Conclusions

32. The decision to conduct a Sector Inquiry into the pharmaceutical sector signified a renewed interest of the Commission in the conduct of companies in relation to exploitation of patent rights. While it could be expected that the core question to be answered by an antitrust sector inquiry led by a competition authority would be whether there are distortions or restrictions of competition in the industry that require antitrust intervention, the Report stemming from the inquiry does not contain competition law analysis, but rather presents the results of an information gathering exercise much akin to other sector inquiries. Yet, the effect was that the questions relating to the management of the antitrust-patent intersection were not addressed at all. At the same time, the tone of the Report sends a message to the industry that the Commission perceives some of its practices as suspicious.[74] While the Commission was at pains throughout the Report to underline that it does not question the underlying value of the patents, the way the Report is phrased suggests the contrary.[75] The focus on the delay of generic entry visible in the Report is indicative of the perception of a tension between competition law and patent rights. In consequence, the statement made at the outset of the Inquiry to the effect that the Commission will not challenge but rather complement intellectual property law could be put into doubt following the publication of the Final Report.

33. Through the inquiry the Commission took an opportunity to make recommendations for the improvements of the conditions of competition through other branches of law, including improvements to the patent system, thus opening an interdisciplinary conversation about the solutions to the perceived problems. However, the momentum and interest in the matter that was built through the inquiry and the public consultation that has accompanied it, has not translated into an insightful competition policy debate, at least not one visible to the outside world. In that sense the Pharmaceutical Sector Inquiry should be treated as only a small step in establishing an approach to the potential problems indicated therein. It showed that further steps are required to build an approach to the issues raised in the report. One would expect that further

74 There have even been suggestions that this was an intentional approach of sending "soft law" messages akin to the US practice of "luncheon law" speech giving in the 1960s and 70s: Kent S Bernard, "The 2008 EC Sector Inquiry Regarding Pharmaceuticals: What Does it Mean From A Research-Based Company Perspective?" (2008) Nov (1) Global Competition Policy, p 10.

75 Nordlander and Spinks (n 60), p 1.

cooperation would be required to achieve that aim. In general, the limited role of sector inquiries as an information gathering exercises raises a question about the role they should play as a tool of competition policy. A question could also be asked about how much the Commission should read out of this particular Sector Inquiry as a basis for further action, given the problems with establishing causation and the insufficient treatment of the innovation dimension that may lead the enforcement activity in the wrong direction.

Chapter 6

Injunctive relief for standard essential patents

I Introduction

1. The question of availability of injunctive relief for holders of standard essential patents (SEPs) is yet another issue at the antitrust-patent intersection in which EU competition authorities used antitrust as a "repair-it-all" mechanism, in a similar they did in *AstraZeneca*. The issue arose in the context of the so called "smartphone wars" between ICT players and so concerns a different, perhaps contrasting industry. It has been addressed first by the Commission in *Motorola*[1] and *Samsung*[2] decisions and then assessed by the Court of Justice in *Huawei v ZTE*[3] (a preliminary ruling decision). Both the Commission decisions and the ruling of the Court of Justice provide an interesting insight into how these authorities approach the balancing exercise of the interests at play and how they perceive the role that antitrust should play in this area. Unlike in the cases explored in the previous chapters, the problem of balancing of short-term goals against long term innovation-based ones is not so visible in that instance, in which the balancing of the diverging interests of breakthrough and follow-on innovators should be the focus of attention instead. However, as it will become apparent from the analysis that follows, antitrust involvement in that form of balancing might suffer from similar problems in that it fails to address arguments based on balancing of the diverging interests at stake.
2. Although both the Commission and the Court of Justice consider seeking injunctions in the SEP context as potentially anticompetitive, they put the balance of interests at a different point. Regardless of the assessment of the differing outcomes reached in those cases, the analysis of the reasoning underlying those decisions shows that they are almost equally deficient in many respects. Although the balancing act expected in those cases required a careful examination of the innovation dimension and of the risks of patent hold up and hold out, these are largely missing from those precedent setting decisions. Instead, the more formalistic and superficial fundamental rights

[1] Case AT.39985 - *Motorola - Enforcement of GPRS Standard Essential Patents*, C(2014)2892 final.
[2] Case AT.39939 - *Samsung - enforcement of UMTS Standard essential Patents*, C(2014) 2891 final.
[3] Case C-170/13 *Huawei Technologies Co. Ltd v ZTE Corp., ZTE Deutschland GmbH*, ECLI:EU:C:2015:477.

approach is applied that leads to a perception of one-sidedness of the decisions which resembles that seen in the decisions analysed in the previous chapters.

3. Before commencing with the analysis of the EU antitrust approach to the question of the use of injunctions in the SEP context as established in the above mentioned decisions, this chapter starts with a more general, context setting discussion that details the interests at play and the nature of the balancing exercise, focusing on the innovation dimension of the problem (section II). It then proceeds to discussing the approach of the Commission (section III) and the Court of Justice (section IV) to the problem. Then, the chapter proceeds to discuss the bottom-line question whether antitrust intervention was warranted in the first place, regardless of the question how it should look like. Section V considers alternative ways of solving the problem through patent litigation or otherwise. It is at this point that a comparison with the US approach is made. The analysis of alternative solutions shows that in case of SEP injunctions the patent system might be much better prepared to face the problem than in the case of abuse of the patent system as it presented itself in the *AstraZeneca* case or in the reverse payment settlement context. While the mechanisms to tackle the issue outside the realm of antitrust enforcement might already exist, Commission's intervention might be seen as a reaction to inadequate use of those mechanisms, thus once again underlining the corrective role played by antirust.

II Standard setting context and the interests at play

4. The effects of antitrust involvement in the question of availability of injunctive relief for SEP holders might be significant for it might affect patent holders' willingness to participate in the standardisation process.[4] The generally positive economic effects of standardisation are recognised by the Commission in its horizontal agreements guidelines,[5] which specify that standards may reduce transaction costs,[6] promote market interpenetration,[7] and help to "maintain and enhance quality, provide

[4] Since unavailability of this remedy in the standardisation context might affect the patent holder's ability to obtain an adequate and timely reward for the their inventive effort. Also, the prospect of antitrust liability itself diminishes the value of the patent and hence reduces the incentive to innovate (Douglas H Ginsburg, Koren W Wong-Erwin & Joshua D Wright, "The Troubling Use of Antitrust to Regulate FRAND Licencing" (October 2015) (1) CPI Antitrust Chronicle, p 7).

[5] Guidelines on the applicability of Article 101 of the Treaty on the Functioning of the European Union to horizontal co-operation agreements [2011] OJ C 11/01, paras 257 ff.

[6] ibid, para 308

[7] ibid, para 263.

information and ensure interoperability and compatibility."[8] The guidelines also emphasise the role standardisation can play for innovation since "[t]hey can reduce the time it takes to bring a new technology to the market and facilitate innovation by allowing companies to build on top of agreed solutions."[9] In this way technical standards encourage "development of new and improved products or markets"[10] thus increasing competition in innovation. Outside the antitrust context, the Commission has been even more vocal about the role of standardisation for innovation, identifying it as an "important enabler of innovation" and a "key instrument for improvement in order to foster innovation".[11] In its Communication dating from 2008 the Commission identified three ways in which standards enable innovation: a) through establishing a level playing field facilitating interoperability, b) by accompanying the emergence of new markets, and c) by contributing to the diffusion of knowledge and facilitation of the application of technology.[12]

5. Yet, the Commission also recognises the risks to innovation that standards may create. Standards themselves may operate to limit innovation by setting detailed technical specifications that exclude alternative technologies and thus limit technological development in respect of the technology they cover. Moreover, when a standard involves the use of a patented technology, a patent holder who owns a patent that is essential for the use of a particular standard might use their controlling position to exclude competitors from the downstream product market by refusing a licence or using their market power to extract excessive royalty rates (the so called patent hold up problem).[13] For this reason standard setting organisations (SSOs), such as ETSI (European Telecommunication Standards Institute) operating in the telecommunications sector,[14] subject patent holders to the requirement to disclose the

8 ibid, para 263.
9 ibid, para 308.
10 ibid, para 263.
11 European Commission Communication of 11 March 2008, "Towards an increased contribution from standardisation to innovation in Europe", COM(2008) 133 final, pp 3 and 2 respectively.
12 ibid, p 3.
13 Horizontal Guidelines (n 5), para 269.
14 ETSI is one of the three official European Standardisation Bodies as provided by the Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations [1998] OJ L 204/37 as amended by Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 [2012] OJ L 316/12.

patents that are essential for the standard in a timely fashion[15] and to commit to license its patent(s) on fair, reasonable, and non-discriminatory (FRAND) terms.[16] The FRAND requirement used by ETSI and other SSOs seeks to ensure a fair balance between the interest of securing access to a standard and the legitimate interest of patent holders to be adequately rewarded for their inventions.[17]

6. Yet, ETSI IPR policy, that is immediately relevant to the cases considered below, is silent on the question of use of injunctive relief against SEP infringers. In general, availability of injunctions as a remedy for patent infringement is guaranteed by the IPR Enforcement Directive, which obliges all Member States to ensure that the "judicial authorities *may* issue against the infringer an injunction aimed at prohibiting the continuation of the infringement".[18] Injunctions need not, however, be automatically available in all cases of infringement, in particular where damages constitute a more appropriate remedy. All the same, they constitute an important tool for the patent holders and can be considered an essential part of patent rights. Still, it is undisputed that the fact that a certain conduct is allowed under national law does not preclude antitrust liability.[19] The question thus arises whether in the specific SEP context where the patent holder committed to licence under FRAND terms, resort to an injunction could constitute an abuse of a dominant position under article 102, the anticompetitiveness of the conduct stemming from patent hold up.

7. It would thus seem that the balancing of interests at play in this scenario would relate to two opposing sets of interests represented on one hand by the patent holders, and by the implementers (licensees) on the other. Yet, as recognised in the Horizontal Guidelines,[20] the interests of the players might be a bit more nuanced if we consider upstream and downstream markets. Upstream-only companies are interested in maximizing the rewards from innovation, downstream-only companies want royalties minimised, whereas vertically integrated companies will have mixed incentives. In the

15 Art 4, ETSI IPR Policy, available at www.etsi.org/images/files/IPR/etsi-ipr-policy.pdf (accessed 1 March 2016); lack of patent disclosure and the subsequent 'patent ambush' have been the subject of a Commission investigation in the *Rambus* decision: Case COMP/38.636 - *Rambus*, of 9 December 2009.

16 Art 6(1), ETSI IPR Policy (n 15); in case the patent holder refuses to commit to licensing on FRAND terms, the standard setting committee might decide not to proceed with the development of a standard (art 8(1)(3) or, in case of standards that have already been developed, request non-recognition of the standard from the European Commission (art 8(2)).

17 Art 3, ETSI IPR Policy (n 15).

18 Art 11, Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights [2004] OJ L 195/16, emphasis added.

19 See to that effect Case C-52/09 *Konkrrentsverket v TeliaSonera Sverige AB* [2011] ECR-I 527.

20 Horizontal Guidelines (n 5), para 267.

world in which telecommunication standards are covered by hundreds or perhaps even thousands of patents,[21] it is likely that vertically integrated companies will not only draw revenue from their patents, but will also need to engage in cross-licensing and potentially have to pay royalties themselves. Moreover, the distinction between the upstream and the downstream markets serves also as a reminder that innovation occurs at both levels. Availability of SEPs allows development of products on the downstream markets of which the SEP technology might form only a small component. For example, the development of the 3G standard in mobile communication, at issue in the *Samsung* decision, allowed for the development of various mobile devices and associated technologies.

8. Thus, in the SEP context the innovation dynamic might be said to be slightly different than in the pharmaceutical cases concerning reverse payment settlements. Here, the SEP user operating on the downstream market is expected to build up on the agreed technological solution and so create follow-on innovation that might in itself create new markets. In the reverse payment settlements context, on the other hand, generic producers were expected to enter the same market as the originator. Their involvement in creating follow-on innovation was expected to be marginal. Rather, their contribution to the innovative process was expected to be realised by exerting pressure on the originator to continue its innovative efforts.

9. Consequently, patent hold up can be considered damaging not only for its potential to affect prices and consumer choice, but also because it might affect the pace of innovation by influencing the development of products utilising the standard on the downstream market. The problem is, however, that although the debate over patent hold up goes back at least to the beginning of the 2000s, empirical studies so far failed to show that patent hold up is a common problem.[22] Determining whether hold up actually took place is a difficult task, in absence of a good counterfactual, and in light of the fact that it is very difficult to determine what constitutes a "fair and reasonable" royalty. Indeed, even patent hold up theory, as advanced by Lemley and Shapiro,[23]

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21 European Commission, Competition Policy Brief, Standard Essential Patents, Issue 8, June 2014, p 2: "More than 23,500 patents have been declared essential to the GSM and the '3G' or UMTS standards developed by ETSI."

22 Anne Layne-Farrar, "Patent Holup and Royalty Stacking Theory and Evidence: Where do We Stand after 15 Years of History?" (2014) OECD Note DAF/COMP/WD(2014)84, p 2.

23 Mark Lemley and Carl Shapiro, "Patent Holdup and Royalty Stacking" (2007) 85(7) Texas Law Review 1991 and "Reply: Patent Holdup and Royalty Stacking" (2007) 85(7) Texas Law Review 2163; see also Carl Shapiro, "Injunctions, Hold-up, and Patent Royalties" (2010) 12(2) American Law and Economics Review 280; that model can be criticised *inter alia* for not taking into account that injunctions are an

whereby bargaining theory is used to show that a threat of an injunction enhances the patent holder's negotiating power in circumstances where the prospective licensee has made a specific investment, has been questioned in other theoretical models analysing the effects of injunctions specifically in the SEP context.[24] Thus, an argument that availability of injunctions to SEP holders is instrumental to creation of patent hold up is based on uncertain foundations. Among other things, general hold up theory ignores the fact that the patent holders might actually have an interest in licensing as widely as possible since it increases their revenues and that standardisation is a repeated game in which an unwillingness to licence on FRAND terms could affect the patent holders' ability to win a standard setting procedure in the future.[25]

10. Some models suggest not only that the problem of patent hold up might be exaggerated, but also that reverse hold up is equally possible and deserves attention in the policy debate.[26] This is to say that, in reality implementers (i.e. SEP users) are just as likely to use the FRAND context to delay reaching an agreement on the royalty rate and pressure the patent holders into licensing on sub-FRAND terms.[27] In absence of a threat of an injunction, the infringers have little to lose by delaying to pay royalties, since damages in Europe are purely compensatory,[28] which suggests that they will be calculated using the FRAND rate.[29] Even if compounded with the litigation cost and interest, the threat of an order to pay damages does not appear to be an effective

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equitable remedy (see Gregor Langus, Vilen Lipatov and Damien Neven, "Standard-essential Patents: Who is Really Holding Up (and When)?" (2013) 9(2) Journal of Competition Law & Economics 253-285, p 254.

24 Peter Camesasca, Gregor Langus, Damien Neve and Pat Treacy, "Injunctions for Standard-essential Patents: Justice is not Blind" (2013) 9(2) Journal of Competition Law & Economics 285-311; Langus, Lipatov Neven (n 23).

25 Damien Geradin, "Reverse Hold-Ups: The (Often Ignored) Risks Faced by Innovators in Standardised Areas" available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1711744 (accessed 1 March 2016), p 7.

26 See n 24.

27 Thus, there are two aspects to reverse hold up - causing loss to the patent holder by delaying to pay and by pressurising them to agree to less advantageous terms which are sub-FRAND.

28 Art 13, Enforcement Directive (n 18).

29 "The precise basis of the award of damages for a SEP in Europe is still untested as there is no known case law. There are continuing debates in some EU Member States (for example, Germany) whether SEP damages should be limited to FRAND royalty, or whether damages might be calculated according to the lost profits of the SEP owner if it is a manufacturing entity, or according to the profits made by the infringer because of the infringement.": Camesasca et al (n 24), pp 298-299; the Commission in the *Motorola* decision (n 1) shortly discussed the question of calculation of damages for SEP infringement referring to the Enforcement Directive and noting that the judicial authorities may order either the recovery of the unfair profits and elements other than economic factors, such as moral prejudice, where appropriate or set the damages "as a lump sum on the basis of the elements, including *at least* the amount of royalties or fees which would have been due if the infringer had requested authorisation to use the IP right in question" (at para 42, paraphrasing art 13 of the Enforcement Directive (n 18), emphasis added).

deterrent, especially in jurisdictions where litigation cost is relatively low. Under such circumstances, the availability of an injunction becomes the only weapon for patent holders against unwilling licensees. To say that eventual availability of damages means that the innovator will in the end receive their reward and that should solve the issue is not telling the whole story, since in the meantime the implementer is allowed to free-ride on the investment made by the innovator by securing an unjustified deferral of the payment to the detriment of the latter through patent infringement. It puts pressure on the innovator to litigate for damages or to let it go and accept sub-FRAND royalties or receive none at all. Consequently, antitrust involvement in the question of availability of injunctions in the SEP context needs to be attentive to the risk of both patent hold up and reverse patent hold up if innovation is not to be harmed.

III The Commission's approach - *Samsung* and *Motorola* decisions

11. The *Samsung* and the *Motorola* decisions, delivered on the same day, set an initial framework for the treatment of injunction requests in the SEP context in the EU. While the former decision is an article 9 commitment decision and contains only a preliminary view of the Commission on the question of the anticompetitiveness of the conduct,[30] the Commission treated both decisions as precedent setting.[31] Both decisions provide that seeking of an injunction by a SEP holder in the FRAND context against a willing licensee may amount to anticompetitive conduct. Both, however, provide for 'safe harbour' under which the patent holder might be justified in doing so, its availability turning on the question of (un)willingness of the licensee to negotiate an agreement. Since the two decisions take virtually the same line on the question of antitrust infringement, they are considered together.

12. There are several elements to consider in the current context in respect of those decisions. These include the basis upon which the Commission decided to intervene as well as the theory of harm, the depth of the engagement with the innovation dimension, the nature of the balancing of interests performed, and the shape of the outcome. It will be seen that the outcomes reached by the Commission in *Motorola*

30 Art 9 of Regulation 1/2003; the *Motorola* decision (n 1) is a prohibition decision under art 7.

31 See to that effect European Commission, "Standard-essential patents", Competition Policy Brief, Issue 8, June 2014, p 1.

and by the Court of Justice in *Huawei v ZTE* serve to represent two different approaches to the question of the role antitrust should play in patent matters.

13. When it comes to the first element listed above, i.e. the basis upon which the Commission decided to intervene, both decisions are phrased in the "exceptional circumstances" language clearly reminiscent of the *Microsoft* decision.[32] Indeed, the *Microsoft* decision is referred to four times in *Samsung* and eight times in *Motorola*. Yet, any comparison of the requests for injunctions with a refusal to supply would be a very imperfect one and indeed one that puts the patent holder in a very bad light.[33] While it is true that a SEP holder could be likened to a holder of an essential facility without which a product on the downstream market cannot be legally produced, not every request for an injunction will be made in circumstances where the patent holder is unwilling to licence on FRAND terms. Indeed, it might be a remedy of last resort against an unwilling licensee.

14. The exceptional circumstances of the *Samsung* and *Motorola* cases, according to the Commission, were respectively the UMTS/GPRS standard-setting process and the fact that the patent holders committed to license the relevant SEPs on FRAND terms and conditions. When discussing the standard-setting context as an element forming the exceptional circumstances of the case, the Commission clearly positioned the discourse within the innovation dimension by pointing out that the GPRS standard, at issue in the *Motorola* decision, is also "important for follow-on innovation as it paved the way for the development of complex communication networks and sophisticated mobile devices."[34] While it noted that Motorola submitted a number of technical contributions to the GPRS standard and that it should be able to obtain FRAND royalties in return for making the technology available, the risks that it associated with the standard-setting and FRAND circumstances were that of patent hold up.[35] At that point it remained silent on the corresponding risk of reverse patent hold up (hold out) and referred to it expressly only in passing later when addressing Motorola's argument that the Commission's action would have a negative effect on the standard setting process.

15. In fact, the position of the Commission on what could undermine the confidence in the standard-setting process was not that it was a risk of reverse patent hold-up, but rather

32 Case T-201/04 *Microsoft v Commission* [2007] ECR II-3601.
33 No such comparison is actually made in the decisions.
34 Para 286.
35 Paras 287-291.

Motorola's seeking and enforcement of an injunction. It rejected the risk of reverse-hold up on the facts, since it considered Apple a willing licensee, but it failed to consider what role a risk of reverse hold up plays in terms of the wider principle set by the precedent established by its decision.[36] The *Motorola* decision opens up with a statement reaffirming the purpose of patent rights as an inventive effort rewarding mechanism[37] and both decisions continue to assert the role that standards can play in encouraging innovation.[38] These statements do not, however, translate to any serious consideration of the effects of the finding of an infringement on those values. This is alarming because ignoring the fact that inability to agree a licence and/or obtain an appropriate royalty in a timely manner can equally have a negative effect on the patent holder and standard-setting could signify a very one-sided approach to the issue. This is particularly so, since the precedent value of the decision was clearly contemplated by the Commission, which actually expressly noted its legitimate interest to find an infringement in circumstances where there was no Union decisional practice on the point, national courts have reached varying conclusions and there was a multitude of ongoing disputes of a similar nature.[39]

16. Still, although the Commission did not expressly consider the risks associated with reverse patent hold up, the framework it set expressly considered the issue of implementer's willingness to agree on licensing terms. Admittedly, the distinction between reverse hold up or hold out and (un)willingness could be regarded as simply one of terminology with both terms being used to address the same problem. Yet, under the terms of the decision, the question of willingness lies within the sole control of the would-be patentee and is a thing that can change over time. So, it appears that the patent holder can still fall prey to reverse hold up without the implementer being found unwilling, since its willingness is assessed only at one point in time, i.e. when the patent holder finally decides to seek for an injunction. To take the example of the *Motorola* decision, there it was not considered relevant that Motorola unsuccessfully tried to conclude a licensing agreement with Apple since 2007 (so for nearly five years) and Apple expressed its willingness to negotiate only at the point when Motorola finally decided to seek for an injunction, to be able to avail oneself of a

36 Only in a footnote it noted that the fact that Apple has been paying royalties into escrow further reduced the risk of reverse hold up (fn 335).

37 Para 29.

38 Paras 22 (*Samsung* (n 2)) and 46 (*Motorola* (n 1)).

39 Paras 555-556.

competition defence. In effect, the risk of reverse hold-up and the question of willingness to reach a licensing agreement as understood by the Commission should not be taken as perfectly concurrent terms.

17. In consequence, the impression that stems from the decision is that it focuses only on "one side of the equation" as can be exemplified by paragraph 418 in which it states that the Decision "promotes the proper functioning of standard setting ... by preventing hold-up" without mentioning the risk of reverse hold-up side-by-side. This perception of the one-sidedness of the approach taken by the Commission might be a result of the prosecutorial role it plays. To justify its prohibition decision it must establish the undertaking's fault. This institutional set up, perhaps subconsciously, pushes the Commission to one side, in which the damning side of the analysis becomes more visible than the part in which it refutes the defendant's arguments. Although the need to disprove the defendant's claims should in theory allow a consideration of both points of view, they do not seem to be examined on an equal footing.

18. Still, the Commission did not deny the patent holder's entitlement to seek and enforce injunctions as part of the exercise of their patent rights. Yet, it considered that in the exceptional circumstances the exercise of that right may be abusive absent an objective justification. In effect, it made the patent holder's exercise of their right *prima facie* suspicious from the competition perspective. At the same time, a parallel risk of reverse patent hold up does not appear to come under competition policy's radar. While the implementers could also be dominant market players, the harm they might cause to the patent holder is not of the type that would immediately be described as anticompetitive. However, if the implementers are active on the same market (as was the case with the telecommunication cases discussed here), such strategies could be said to unfairly prejudice a competitor.

19. In line with the general case law on the issue of justifying conduct which might otherwise be caught by an article 102 prohibition, the Commission explained that an undertaking would need to show that conduct was either objectively necessary or that its effects were counterbalanced or outweighed by the efficiency gains that also benefit consumers.[40] The Commission did not consider that the need to protect IPR could in itself constitute a justification for seeking an injunction, because then the exception could never apply. Equally, in *Samsung*, it considered that the conduct could

[40] Para 421.

not be justified by the public interest in an effective standardisation process or potential efficiencies.[41] Instead, the Commission considered that in some circumstances the patent holders could be justified in protecting their commercial interests and named three (apparently non-exhaustive) scenarios: 1) when the potential licensee is in "financial distress and unable to pay its debts", 2) when the licensee's assets are "located in jurisdictions that do not provide for adequate means of enforcement of damages", or, most significantly, 3) when the potential licensee is unwilling to enter into a licence agreement on FRAND terms.[42] This separation of protection of commercial interests from protection of IPR is curious for the commercial interests at issue arise precisely because of the existence of IPR and are not really separable.

20. Essentially, both decisions turned on the question of (un)willingness to agree FRAND terms. Indeed, Motorola in its response to the complaint conceded that its entitlement to seek injunctive relief was limited in the SEP FRAND context,[43] since it has committed to license its patent and so the availability of injunctions was limited to unwilling licensees. However, it understood the issue of willingness to license differently. Its understanding of willingness relied on the interpretation created by the German courts stemming from the *Orange-Book-Standard* judgment.[44] The German law on granting of injunctions for patent infringement is considered very generous towards patent holders which is one of the reasons why Germany is a very popular destination for patent litigation.[45] Under the German interpretation a defendant in an infringement action could avail oneself of a competition defence in an action for an injunction only if it made an unconditional offer to conclude a license agreement with the patent holder.[46] A defendant would not be considered a willing licensee (i.e. one that has made an unconditional offer to the patent holder) if it was intending to challenge the validity of the patent or patent infringement. This curtailment of the right to challenge the validity of SEPs was one of the main reasons why the Commission objected to Motorola's conduct.

41 Para 65.
42 Para 67 (*Samsung* (n 2)), para 427 (*Motorola* (n 1)).
43 Para 297.
44 Case No KZR 39/06 of 6 May 2009; see paras 50-52 for further details on the approach of the German courts.
45 Alison Jones, "Standard-essential patents: FRAND commitments, injunctions and the smartphone wars" (2014) King's College London Dickson Poon School of Law Legal Studies Research Paper Series, paper no. 2014-19, p 10.
46 Para 82, *Motorola* (n 1).

21. According to the Commission, Motorola's rejection of six consecutive offers from Apple *inter alia* on the grounds that the offer was not unconditional was an illustration of the fact that Motorola was able to use the threat of an injunction to pressure Apple to accept disadvantageous terms which it would not have otherwise accepted under normal bargaining conditions.[47] It considered that it was not the underlying value of the patented technology which drove the negotiation process, but rather the threat of being excluded from the market and the corresponding loss of sales.[48] Yet, this is precisely where the value of a patent injunction as a remedy lies. Significantly, the Commission's assessment of the nature of the terms of the Settlement Agreement did not directly relate to the question of what would amount to a FRAND royalty rate, but rather to the inclusion of additional terms such as the non-challenge clause and acknowledgement of Motorola's claims for past damages. Still, it considered that some of the terms of the Settlement Agreement induced by Motorola through a threat of injunction limited Apple's ability to influence the level of royalties.[49]

22. In fact, the Commission analysed the offers made by Apple in quite considerable detail in order to conclude that the second offer was enough not to consider Apple unwilling to enter into a licence agreement on FRAND terms.[50] The Commission's scrupulousness of analysis in respect of the non-challenge clauses should be applauded – it even took into account the details of how the German patent enforcement system works.[51] It was definitely right to conclude that non-challenge clauses would be contrary to the public interest in ensuring effective competition. In stating so, the Commission was concerned equally with the effects on prices resulting from the potential for licensees paying royalties for invalid IPRs and the resulting higher costs of products which could be passed on to the consumers[52] and the effects on innovation. In respect of the latter aspect it referred to the 2004 Technology Transfer Guidelines which state that:

> [...] in the interest of undistorted competition and in conformity with the principles underlying the protection of intellectual property, invalid

47 Para 411.
48 Para 324.
49 Paras 336-339.
50 Para 307.
51 The German system is a 'bifurcated' system in which questions of infringement and validity are considered separately, with the courts adjudicating on infringement not having a competence to rule on the question validity.
52 Para 377.

> intellectual property rights should be eliminated. Invalid intellectual property stifles innovation rather than promoting it.[53]

It has also further concluded, after discussing it in some detail, that Settlement Agreement termination clauses applicable in the event of a validity or an infringement challenge do not meet the efficiency defence standard, thus refuting a claim by Motorola that termination clauses in general maintain the incentives of licensors to innovate.[54] The Commission countered Motorola's assertion by stating that "innovation cannot be said to be driven by investments in invalid patents which should not have been granted in the first place" and that there is no public interest in protecting patents granted in error which by definition do not represent valuable technology innovation.[55]

23. It is also worth noting that while, as discussed at the beginning of this section, the decision as a whole is explained in terms of exceptional circumstances of the case, Motorola's attempt to shield oneself from invalidity challenges was treated as a distortion of competition on the merits.[56] It can be recalled that this standard for justifying intervention was used in the *AstraZeneca* case, discussed and criticised in chapter 4. This multitude or perhaps even a discrepancy of standards of intervention in the patent context should be borne in mind for the discussion to be had in the following chapters.[57]

24. The engagement of the Commission with the innovation dimension in respect of the effects of the non-challenge clauses is a positive sign. Yet, it would seem that this additional damning circumstance of the *Motorola* case, which could possibly be considered anticompetitive in its own right, might have sidetracked the Commission from the general principle concerning seeking of injunctions in the SEP context that it was about to establish. The core of the decision, in so far as it was precedent setting, should be the balancing of the general interests that are at play in the injunction

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53 Commission Notice, Guidelines on the application of Article 81 of the EC Treaty to technology transfer agreements, (2004) OJ C-101/02, recital 112; these have since been replaced by the Communication from the Commission, Guidelines on the application of Article 101 of the Treaty on the Functioning of the European Union to technology transfer agreements (2014) OJ C-89/03, which contain the same statement in recital 134.

54 Para 481.

55 Query how such statements could be used in the reverse payment settlement context, discussed in chapter 3, where the general value of settling claims, including patent claims, has been recognised.

56 Para 383.

57 See ch 10 in particular.

seeking scenario and establishing a clear standard to follow in future cases. Yet, there is no parallel discussion of the innovation dimension in respect of that core issue to be found in the Decision outside the particular German litigation context.

25. While the above points to how close the Commission's analysis was to the facts of the particular case before it, on the whole it could be said that it showed mixed sensitivity to the industry context at hand. On the one hand, it noted the fast moving nature of the mobile devices market when discussing losses to Apple stemming from an injunction, but at the same time it seemingly ignored (or rejected without discussing it) the precarious position of Motorola stemming from it not receiving its reward in a timely fashion while Apple was allowed to free-ride on its R&D effort. Equally, the interrelationship between the parties and in particular Apple's countervailing bargaining power was addressed only at the level of establishing dominance, but it was not examined when discussing the potential for hold up. This is despite the fact that the differing incentives of various market players are specifically mentioned in the Horizontal Guidelines,[58] a soft law document to which the Commission referred several times in the decision. Moreover, the fact that standard setting is a repeated game, a feature which might be very significant to the way the ICT industry works, was again not scrutinised in connection patent hold up.[59] Both of these industry characteristics are directly related to the question of patent hold up and so to the question of potential of damage to innovation, so it might be considered disappointing that the Commission has not paid more attention to that aspect.

26. Another feature of the analysis in the *Motorola* decision that is worth noting is a section that appears towards the end of the decision, following the conclusions on the question of abuse and eventual existence of an objective justification, which is an additional section devoted specifically to the question of balancing of the fundamental rights and freedoms at stake. The three fundamental rights enshrined in the Charter recognised by the Commission as relevant to the case were the rights linked to IP (article 17(2)), right of access to a tribunal (article 47) and the freedom to conduct a business (article 16). While the first right clearly pointed in favour of protecting the

58 See para 7 above.

59 Instead, in the section devoted to dominance (paras 263-164) the significance of standard-setting as a repeat game was rejected on the grounds that Motorola has not submitted any concrete evidence about whether and how Motorola could be constrained by such considerations and the fact that any such effects would be dependent on the future market situation, which can quickly significantly change, given the nature of the market. It could be presumed that the Commission would apply the same reasoning in the assessment of anticompetitiveness and indeed it might be a reason why it did not consider this argument in the patent hold up context.

interests of Motorola as a patent holder, the right to access to a tribunal was taken to apply to both Motorola and Apple (because of the existence of non-challenge clauses), and the right to conduct a business was (curiously) only taken to apply to Apple's freedom to conduct a business without recognising the parallel restraints on Motorola's freedom to conduct a business.

27. Positioning the right to conduct a business as pointing in the opposite direction to exercise of IP rights is already unusual, especially since it appears to extend to accepting conduct which in reality amounts to patent infringement as coming within the scope of that right. However, it is even more astonishing to see that the Commission was of the opinion that "an interpretation which ensures a greater enjoyment of the freedom to conduct a business, while at the same time not adversely affecting the substance of an IP right, should be favoured."[60] As a matter of patent policy it is accepted that a freedom to conduct a business by those who wish to use patented technology might be limited in order to pursue the objectives of patent law and yet the above statement by the Commission seems to call that policy into question and allow for a new rebalancing clearly favouring anti-IP interpretation whenever possible focusing on limiting the cost of the patent system. The Commission concluded that the restriction on Motorola's rights was not disproportionate and necessary, despite accepting that the "right of the patent holder to oppose infringements forms part of the specific subject matter of that property."[61] Justifying such conclusion simply by relying on Apples' right to conduct a business does not seem very persuasive.

28. While the phrasing of the discussion in terms of fundamental rights could be a positive sign, since it could serve to highlight the importance of intellectual property rights at issue in the decision, it might have actually had the opposite effect. The fundamental rights approach pursued by the Commission is necessarily formalistic and had the effect of taking the Commission away from the more economic, innovation centred discussion, in which the incentives and interests of the parties to the decision are balanced against each other. Instead, the balancing of fundamental rights exercise appears to have the aim of ensuring that the limitations on the availability of patent remedies resulting from the decision do not indeed breach fundamental rights. This conclusion is strengthened by the fact that the fundamental rights discussion is only

60 Para 507.
61 Para 502, references omitted.

conducted at the end of the analysis and does not form an integral part of the discussion of the anticompetitiveness of the conduct at play. Equally, the initial part of the *Motorola* decision also refers to the TRIPS Agreement and the Enforcement Directive, but only to confirm that they allow for limitations of the remedies available to the patent holders.[62]

29. The above analysis of the reasoning underlying the Commission's decision in *Motorola* reveals some problems which arguably are reflected in the outcome, which shows some signs of one-sidedness. While the *Samsung* decision, being a commitment decision, established a clear procedural framework to follow (whereby a potential licensee has 60 days to sign an invitation to negotiate which would be followed by 12 month of negotiations, failing which there would be a third-party determination of FRAND terms), no equivalent can be found in the *Motorola* decision. The effect of that was to put the implementer in the upper-hand position, since even in case of considerable delay it could always change its mind at the very last moment once the patent holder started to seek for an injunction. This is because past unwillingness would be irrelevant to the question of the patent holder's liability, as the Commission itself determined in the *Motorola* decision.[63]

30. The *Motorola* decision is a step back from an extreme pro-patent holder position taken by the German courts in which injunctions are granted almost as of right and it is very difficult for an implementer to avail oneself of a competition defence to the far pro-implementer side of the spectrum.[64] It creates a large 'safe harbour' for the infringers, rather than for the patent holders, that encourages delaying tactics.[65] As it will be discussed in the next section, the *Huawei v ZTE* decision achieves a middle ground in terms of the balancing of interests albeit in a rather interventionist way.

IV The Court of Justice's take on SEP injunctions - *Huawei v ZTE*

31. The preliminary ruling decision of the Court of Justice in *Huawei v ZTE* delivered just over a year after *Motorola* and *Samsung* is another case stemming from patent litigation before the German courts. The litigation concerned infringing use of a SEP

62 Referring to art 8(2) of the TRIPS Agreement and art 3(2) of the Enforcement Directive (n 18).

63 Para 441.

64 See paras 20-21 above and paras 50-51 below for a further discussion.

65 Pedro Henrique D Batista, Gustavo Cesar Mazutti, "Comment on 'Huawei Technologies' (C-170/13): Standard Essential Patents and Competition Law - How Far Does the CJEU Decision Go?" (18 February 2016) IIC, p 4.

owned by Huawei pertaining to the LTE standard, and so was another case coming from the ICT sector. The German court wanted to know under what conditions specifically the actions of the patent holder seeking an injunction in the FRAND context could be considered abusive under article 102 and whether the implementer's willingness to negotiate should be considered sufficient for them to be able to avail themselves of a competition defence against an injunction.

32. Similarly to the Motorola's decision the Court held that the patent holder's conduct could be in the exceptional circumstances abusive. However, unlike the Commission, it proceeded with giving more detailed guidance to the Landgericht Düsseldorf court by establishing a particular framework specifying what steps need to be followed respectively by both the patent holder and by the infringer if they want to avoid being accused of acting anticompetitively or want to avail themselves of a competition defence.[66] The imposition of obligations on both parties could be said to be reflective of the more balanced approach adopted by the Court in that respect. Similarly, the Advocate General in that case considered that "a finding of abuse of a dominant position in the context of standardisation and the commitment to license an SEP on FRAND terms can be made only after the conduct not only of the SEP-holder but also of the infringer has been examined." In that respect, the facts of the case, as presented by the referring court, might have been influential on the reasoning of the Court, since it was understood that neither party could be clearly considered unwilling to negotiate,[67] in contrast with *Motorola* where the Commission clearly objected to the attitude of Motorola. So, it might be that the facts of the case before the Court lent themselves to a more balanced approach.

33. In providing a specific procedural framework for the parties to follow, the Court could be said to have taken a rather creative take on the requirements of article 102 TFEU, since it might be considered a stretch to claim that article 102 prescribes a particular

66 Under the framework set by the Court the SEP owner needs to alert the infringer of the infringement and, after the implementer expresses a willingness to conclude a licensing agreement on FRAND terms, provide them with a written offer specifying the terms of the licensing agreement including the amount of royalty claimed. The infringer is then expected to diligently and in good faith reply to the offer without employing delaying tactics. In the event they do not agree with the terms of the offer, they are to present a FRAND counter-offer. If the negotiations prove to be unsuccessful the parties are expected to agree to a third-party determination of FRAND terms if they do not wish to be regarded as unwilling to reach an agreement. From the fact that both an offer and the counter-offer can be FRAND and the parties might still end up in disagreement it might be induced that FRAND indeed is a range, rather than a definitive point (Nicolas Petit, "Huawei v ZTE: Judicial Conservatism at the Patent-antitrust Intersection" (October 2015) (2) CPI Antitrust Chronicle, p 7).

67 Para 35 of the judgment (n 3).

course of conduct that entails following a set of steps by both sides to a case. It could be said to be taking special responsibility owed by dominant firms under article 102 one step further. However, in prescribing a specific course of conduct the Court behaved very pragmatically, by offering a structure where otherwise there was none. In effect, it filled in the gaps where other sets of regulation, including private regulation offered by ETSI, failed to offer a solution. At the same time, while the solution offered by the Court of Justice could be considered proactive, it is structured in a way so as to avoid any antitrust inquiries as to what constitutes FRAND terms.[68]

34. The outcome of the case could thus be considered a step forward from the innovation perspective, by resolving a problem of inability to reach a licensing agreement in a balanced way by putting obligations on both the infringer and the patent holder. Yet, the decision leaves a number of issues unresolved. Firstly, it provides for no specific timeframe – the decision whether the parties are stalling is left to the national courts to decide on a case-by-case basis. The only guidance in that respect is provided by the Advocate General Wathelet who stated that this must be assessed in light of the "'commercial window of opportunity' available to the SEP-holder for securing a return on its patent in the sector in question."[69] It might have been right for the Court not to impose a strict time framework on the parties, not only because it could be viewed as overstepping its boundaries, but also because the question of the actual seriousness of the parties' willingness to reach an agreement should be a matter of factual assessment on an individual basis. However, it is not inconceivable that arguments will arise in the future as to whether a licensee is trying to stall and it will be the patent holder who will ultimately bear the risk of getting it wrong by risking antitrust liability.

35. In the same vein, both the Court of Justice and Advocate General Wathelet underlined that, in line with settled case law, the concept of abuse is an objective one.[70] Although not new, this statement takes on a particular significance in the present context, since it has the effect of an apportionment of risks in the negotiation process set up by the Court. When making an offer or a counter-offer it is the party who makes it that bears the risk of getting it wrong. Yet, if the offer is later determined not to amount to a FRAND offer, the consequences for the patent holder are more significant than for the implementer. Unlike the would-be-licensee, the patent holder risks antitrust liability,

68 See para 43 for a discussion whether this goal has been actually achieved.
69 Para 89 of the AG Opinion.
70 Para 68 of the AG Opinion, para 45 of the judgment (n 3).

since their seeking of an injunction immediately becomes potentially anticompetitive, even if the offer not being FRAND is a result of a bad assessment made in good faith. As a result, the patent holder might be more likely to err on the lower end of the scale of royalty rates if it wants to preserve the possibility of using the injunction remedy should negotiations fail. The potential ramifications of that situation, however, are not considered in any detail by the Court.

36. While the Court is clear that in establishing the framework for action it tries to ensure a fair balance between the interests concerned,[71] the judgment does not provide much detail on the balancing exercise it performed. Although it invokes the referring court's opinion that the position of both the SEP holder and the infringer should not make it possible for them to create either a patent hold-up nor a reverse hold-up situation, it does not consider the issue itself. The language of neither patent hold-up nor hold-out enters its deliberations. The economic underpinning that would form a theory of harm is not addressed in the decision. The balancing act to be performed is phrased directly as a balance between free competition and the requirement to safeguard patent holders' rights and their rights to effective judicial protection.[72] The innovation implications of the new framework are not, however, expressly considered anywhere in the decision. Instead, the Court concentrates on the details of the procedural framework it creates, without innovation playing a prominent role in the discussion.

37. Similarly, the Advocate General's Opinion is scant of any discussion of the risks of (reverse) patent hold up going beyond an analogous invocation of the referring court's opinion that these risks need to be balanced out. Only in a footnote referring to the possible under- or over- protection of the patent holder under the *Samsung* decision and the *Orange-Book-Standard* judgment he noted the ZTE's (the implementer's!) opinion that "placing reliance only on the alleged infringer's mere 'willingness to negotiate' would result in pricing which falls well below the true economic value of the SEP" just as reliance on the *Orange-Book-Standard* would create an opposite problem.[73] This possibility of one party exerting pressure on the other one, depending on how the balance of interests is set by the Court, is not expanded upon in the Advocate General's Opinion.

71 Para 55.
72 Para 42.
73 Fn 20.

38. Instead, the Opinion of the Advocate General is couched in the fundamental rights terminology in the same way as the Commission's decision at the expense of a more economic approach that would inquire into effect on the incentives of the parties and on innovation.[74] Yet, while the Advocate General's Opinion refers to a freedom to conduct a business,[75] this right is not referred to in the judgment. In a like manner, the Court does not pick up on the opinion expressed by the Advocate General that a commitment to grant licenses on FRAND terms in analogous to a 'licence of a right'.[76] The Advocate General treated the situation as analogous to 'licences of right' under article 8 of Unitary Patent Protection Regulation under which a proprietor of a unitary patent may file a statement to the effect that they are "prepared to allow any person to use the invention as a licensee in return for appropriate consideration".[77] A licence obtained in this way is to be treated as a contractual licence.[78] From there the Advocate General continued to state that an injunction should not in principle be issued against a patent licensee who has a license of a right. That analogy of a FRAND commitment to a 'licence of a right' by the Advocate General appears contradictory and incoherent in terms of his own analysis, since only a few paragraphs above he states that Huawei did not waive its right to bring actions for prohibitory injunctions by making a FRAND commitment.[79] Indeed, this is a conclusion flowing from the opinion read as a whole.

39. Still, the judgment and the AG's opinion in many respects go hand in hand. For example, the Court refers with approval to the Advocate's General Opinion that the facts of *Huawei v ZTE* should be distinguished from the cases on refusals to supply, thus dispelling a connotation alluded to in the *Motorola* decision arising out of the use of the exceptional circumstances standard. Since Huawei, as a member of ETSI, voluntarily committed to that standard setting organisation to license its SEPs on FRAND terms and conditions, *prima facie* its conduct could not be treated as a refusal to supply, meaning that the case law on the refusals to supply could only be partially

74 Lundqvist describes his approach as 'legalistic'; Björn Lundqvist, "The interface between EU competition law and standard essential patents – from Orange-Book-Standard to the Huawei case" (2015) European Competition Journal, p 17

75 Para 59.

76 Para 65.

77 Regulation (EU) No 1257/2012 of the European Parliament and of the Council of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection, (2012) OJ L361/1.

78 ibid, art 8(2).

79 Para 59.

applicable to the dispute at hand. Recognising this distinction shows some sensitivity to the different dynamics of the case at hand.

40. Nonetheless, as stated at the beginning of this section, the justification for limiting the patent holder's ability to exercise their intellectual property rights is explained by the exceptional circumstances standard in the same way as in the *Motorola* decision. Yet, both the Advocate's General Opinion and the judgment of the Court of Justice also refer to another formulation, one already known from the *AstraZeneca* case discussed in chapter 4, that is "recourse to methods different from those governing normal competition".[80] Both the 'normal competition' and the 'exceptional circumstances' standards suffer from the same weakness – they do not allow to predict in advance what sort of conduct might fall within the ambit of antitrust scrutiny.[81] However, there is a slight difference between the two: the former entails a theory of harm, while the latter only provides for a justification for interfering with intellectual property rights with the theory of harm to be looked for elsewhere. Moreover, so far, the latter has been used almost exclusively in respect of cases involving intellectual property rights, while the former has been applied in a variety of contexts. The 'recourse to methods other than normal competition' should be treated as akin to the 'competition on the merits' referred to in the *Motorola* decision in respect of the non-challenge clauses.

41. Although not as prominently as in the *Motorola* decision, the judgment and the Opinion also touched on the question of challenges to patent validity or infringement and confirmed the position taken by the Commission in that respect. In that sense the Court of Justice too is distancing itself from the *Orange-Book-Standard* line of case law.

V Is antitrust involvement necessary?

42. The above analysis of the case law did not call into question the desirability of the antitrust bodies' involvement in the issue of SEP injunctions, but instead concentrated on the questions of how the Commission and the Court justified their interventions, what kind of reasoning informed the balancing exercise at hand and with what result,

[80] AG's Opinion: paras 68 and 73; para 45 of the judgment (n 3); relying on earlier case law, including Case 85/76 *Hoffman-La Roche v Commission* [1979] ECR 461, para 91; Case C-62/86 *AKZO v Commission* [1991] ECR I-3359, para 69; Case C-52/07 *Kanal 5 and TV 4* [2008] ECR I-9275, para 25; and Case C-52/09 *TeliaSonera Sverige* [2011] ECR I-527, para 27; C-549/10 P *Tomra Systems and Others v Commission* ECLI:EU:C:2012:221, para 17.

[81] See further ch 10.

paying particular regard to the innovation dimension. Imposition of antitrust liability, however, is a crude remedy that can come at a heavy cost.[82] This in turn raises the question whether antitrust involvement was really necessary in the first place, i.e whether there exist alternative ways of solving the problem (assuming of course that a problem indeed exists[83]).

43. As the Advocate General Wathelet pointed out himself at the outset of his Opinion in *Huawei v ZTE*, many of the problems arising in the SEP injunction context arise from lack of clarity as to what amounts to FRAND terms, a conceptual problem that could be better resolved in the context of other branches of law.[84] Indeed, competition law involvement as delineated by the Court of Justice carefully avoids entanglement with those very questions and pushes them back to the competent judges or arbitrators. As things stand now, it might be that these questions will continue to affect only patent courts, even if in a context of a competition defence, yet the possibility remains that in the future the Commission or eventually the Court of Justice will be forced to decide also on FRAND questions, following a complaint alleging that a patent holder has acted anticompetitively before seeking an injunction because its offer was not FRAND.

Standard Setting Organisations (SSOs)

44. This uneasy situation would call for a greater involvement of ETSI. In fact, both the Commission decisions in *Motorola* and *Samsung* and the judgment of the Court of Justice in *Huawei v ZTE* note the limited role played by ETSI after the establishment of a standard, perhaps in an attempt to push for a reaction from that SSO (*signalling*). The primary purpose of SSOs like ETSI is to facilitate a consensus driven adoption of standards. So, it is above all a platform for engineers and scientists to discuss various technical solutions. Although formally recognised as a European Standardisation Body,[85] ETSI remains a private organisation[86] with no enforcement powers.

82 Although no fine was imposed in *Motorola* (n 1) on the grounds that it was a novel case, such a possibility cannot be ruled out in the future.

83 See the discussion on the existence of patent hold up in section II.

84 Para 9; the Opinion does not specify what branches of law are meant, but presumably it could be a matter for either general contract law or patent law.

85 Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations, OJ L 204/37.

86 On the mixed private-public role played by the SSOs see, Jorge L Contreras, "From Private Ordering to Public Law: The Legal Frameworks Governing Standards-Essential Patents" (2017) 30 Harvard Journal of Law and Technology 211.

Nonetheless, ETSI and other SSOs have been arguably quite responsive to competition concerns that might arise in the standardisation context.[87] The inclusion of IPR policies, requiring patent disclosure and a commitment to licensing on FRAND terms as a condition to a patent solution becoming a standard are ways to prevent patent ambush and patent hold up. Yet, although it has an IPR Policy that subjects the establishment of a standard involving a SEP to a requirement of a FRAND commitment, ETSI does not involve itself with the licensing negotiations or even with deciding whether a given patent is indeed a SEP (it only relies on declarations by the interested parties).

45. Indeed, *ex ante* negotiations concerning licensing terms could be regarded as anticompetitive price-fixing agreements, since SSO IPR policies are after all agreements between its members who are manufactures and thus competitors. Still, DoJ has previously issued Business Review Letters in which it approved SSO IPR policies in which members were required or permitted to disclose key licensing terms before a standard has been adopted and to specify the maximum level of royalties.[88] The policies were approved on the grounds that they allowed SSO members to "make more informed decisions when setting a standard" and reduce a risk of patent hold up, while at the same time they prohibited discussing prices at which end products would be sold or joint negotiation of licensing terms.[89]

46. A more recent IEEE IPR policy has sparkled more controversy. It contained terms specifying the way in which FRAND should be calculated and also prohibited the use of injunctions in the FRAND SEP context. This policy was also cleared by the DoJ, but some doubts have been expressed as to whether it would not be found anticompetitive under EU competition rules.[90] The possibilities of tackling competition problems by the SSOs might be thus limited,[91] even though varying composition of those organisations, including both pure innovators, implementers and

87 Anne Layne-Farrar, "Proactive or reactive? An empirical assessment of IPR policy revisions in the wake of antitrust actions" (2014) 59(2) The Antitrust Bulletin 373.

88 IPR Policies adopted by VITA Standards Organisation in 2006 and by IEEE (Institute of Electrical and Electronics Engineers) in 2007; see Lisa Kimmel, "Standards, Patent Policies, and Antitrust: A Critique of IEEE-II" (2015) 29(3) Antitrust 18, 19.

89 Response to VITA available at https://www.justice.gov/sites/default/files/atr/legacy/2006/10/31/219380.pdf (accessed 7 February 2017; Response to IEEE, available at https://www.justice.gov/sites/default/files/atr/legacy/2007/04/30/222978.pdf (accessed 7 February 2017).

90 Nicolo Zingales and Olia Kanevskaia, "The IEE-SA patent policy update under the lens of EU competition law" (2016) European Competition Journal.

91 Inversely, ETSI has also adopted guidelines on antitrust compliance.

vertically-integrated companies, should ensure that diverging interests and needs are accounted for without government involvement.[92] With the involvement of the Commission, the FTC and the DoJ, ETSI has also discussed adopting a policy concerning injunctions, but no consensus on that issue has been reached as of yet.[93]

47. Another way in which the SSOs could contribute to solving of the problem of injunctions in the SEP context would be to promote Alternative Dispute Resolution (ADR). This could be done on a voluntary basis or perhaps even by prescribing a particular course of conduct in the event of a disagreement over FRAND terms or willingness to license as part of the SSO IPR policy. The possibilities of creating a detailed practical solution on the part of the SSOs might be in this respect greater than those of the Court of Justice in handling preliminary rulings.

A contractual solution

48. Apart from the theoretical possibility of ETSI and the like standardisation bodies providing a framework for the patent holders and the infringers to resolve their differences in negotiating a license agreement, another possibility would be to look for a contractual solution arising out of the FRAND commitment itself. In fact, the *Motorola* decision partially recognises the capability of a FRAND commitment to prevent competition concerns from arising. [94] Whether FRAND commitments could be enforced like contracts is far from clear though.[95] The answer to the question whether they constitute a contract, an offer, or a mere invitation to treat would vary from one Member State to another.[96] Yet, even if it were possible to enforce them, it has been argued that the infringers would have no interest in suing, since they would simply pass the above-FRAND price down to the consumers.[97] Yet, this argument is simply not reflective of reality. If it were the case, they would do so now, and there

92 For a view that government involvement in SSO IPR policy setting should be limited see Koren W Wong and Joshua D Wright, "Intellectual Property and Standard Setting" (2016) 17(3) The Federalist Society Review 52, 52.

93 http://www.etsi.org/news-events/news/732-2013-12-news-release-ipr-committee (accessed 7 Februrary 2017).

94 Para 77.

95 FRAND commitments have in the past been considered as contractual commitments in the US, see, *Microsoft v. Motorola*, Case No. C10-1823JLR (W.D. Wash. Sept. 4, 2013); *Apple v. Motorola, Inc.*, 869 F. Supp. 2d 901, 913–14 (N.D. Ill. 2012); *Microsoft Corp. v. Motorola, Inc.*, 696 F.3d 872, 884–85 (9th Cir. 2012).

96 Pedro Henrique D Batista, Gustavo Cesar Mazutti, "Comment on 'Huawei Technologies' (C-170/13): Standard Essential Patents and Competition Law - How Far Does the CJEU Decision Go?" (18 February 2016) IIC, p 8.

97 George S Cary, Mark W Nelson, Steven J Kaiser and Alex R Sistla, "The Case for Antitrust Law to Police the Patent Holdup Problem in Standard Setting" (2011) 77(3) Antitrust Law Journal 913, p 941.

would be no arguments over injunctions. SEP users have an incentive to undercut their opponents, so they will use every opportunity to capture the market, even if that involves vindicating their rights in courts.[98] The problem lies rather with the enforceability of the FRAND commitment.

The patent system

49. Ultimately, however, the most obvious solution would appear to be to leave it to the patent courts to decide whether an injunction is warranted in a particular case. As pointed out above, the Enforcement Directive, which provides a bottom line in terms of patent protection in the EU, seeks to ensure that Member States offer remedies that are not only effective and dissuasive, but also proportionate (article 3(2)). It also specifies that remedies "shall be applied in such a manner as to avoid the creation of barriers to legitimate trade and to provide for safeguards against their abuse" (article 3(2)) and that they should be "fair and equitable (article 3(1)). Article 11 of that Directive, which provides that Member States shall ensure that judicial authorities may issue an injunction against an infringer aimed at prohibiting the continuation of the infringement, should be read in light of the requirements of article 3 indicating the general nature of remedies. Indeed, this has been the approach taken by the English courts.[99]

50. While the Enforcement Directive aims to harmonise the issues relating to IP enforcement across the EU, the approach of the Member States to the question of patent injunctions varies. The strong pro-patent holder position of the German courts might be said to be the trigger for the antitrust decisions discussed above. The position of the German courts on the issuance of injunctions stemmed from the decision of the Supreme Court in the *Orange-Book Standard*. The case itself did not concern a patent that was a SEP subject to a FRAND obligation, but rather one in respect of which licences have already been granted on FRAND terms. The validity of the said patent was also already established, a circumstance which is relevant in the German bifurcated patent litigation system in which questions of infringement and validity are considered separately. The requirement to provide an unconditional offer to conclude a licence that contains an non-challenge clause looks very different in such

98 Douglas H Ginsburg, Taylor M Owings and Joshua D Wright, "Enjoining Injunctions: The Case Against Antitrust Liability for Standard Essential Patent Holders Who Seek Injunctions" (October 2014) theantitrustsource, p 5.

99 *HTC v Nokia* [2013] EWHC 3778 (Pat), [26].

circumstances. Yet, the decision of the Supreme Court was applied by the lower courts also in the SEP FRAND context in respect of patents whose validity has not yet been tested before the courts. In effect, the balance of the system was against the infringers who were not only prevented from challenging the patent,[100] but also were required to provide a deposit for damages and render "super-FRAND" payments in respect of past patent use if they wished to avoid an injunction. At the same time, the SEP holder was not obliged to get involved with the offer made by the infringer or to make a counter-offer.[101]

51. In consequence, the German courts were rarely willing to deny an injunction. Rather than granting them as a matter of discretion to ensure the proportionality of the remedy, they granted them more as of right. The competition law defence as interpreted under the *Orange-Book Standard* was hardly available to the infringers unless they were willing to forfeit any patent defences they might have had.[102] Thus, it could be argued that the approach of the German courts to the issue of injunctions induced the Court of Justice and the Commission to cast doubt upon the patent courts' ability[103] to balance the interests at stake themselves. Yet, the Commission in *Motorola* did not openly question the German approach, but rather distanced itself from the *Orange-Book-Standard* line of case law by distinguishing the facts of that case, which admittedly did not concern a SEP (although it was subsequently applied also in SEP context). In effect, it could be said that antitrust law again acted as a repair-it-all mechanism.[104]

52. On one reading, the approach of the German courts could have been just a misinterpretation of the *Orange-Book Standard* made by the lower courts that has not been corrected in time by the German Supreme Court.[105] Yet, the German courts were not isolated in treating injunctions as a remedy which is granted almost automatically. Other major civil law jurisdictions, such as France, also grant injunctions almost

100 See e.g. *Motorola Mobility Inc v Apple Sales International* Regional Court of Mannheim, 7th Civil Division, 9 Dec 2011, 7 O 122/11, and Karlsruhe Court of Appeal, 30 Jan 2013, 6 U 136/11.

101 Jones (n 46), p 12.

102 It seems that the only other way to avoid an injunction would be by proving to a high degree of probability that the patent was invalid: Jones (n 46), p 11.

103 ibid, p 7.

104 Still, at least the Court of Justice acted as a result of a specific request from the German Court with a view to that national court applying its guidance on it s own to the case before it.

105 Injunction cases hardly ever get appealed, since implementers agree to a licence in order not to continue being excluded from the market: Jones (n 46), p 12.

whenever requested.[106] Not all of the Member States decided to make use of the optional article 12 of the Enforcement Directive, which provides an option to use alternative measures *inter alia* when grant of an injunction would cause the defendant "disproportionate harm and if pecuniary compensation to the injured party appears reasonably satisfactory". In that respect, one may speak of a civil law vs. common law divide, since in the UK an injunction is an equitable remedy granted as a matter of the court's discretion which might be replaced by an award of damages *in lieu* if they are an adequate remedy.[107] In practice, however, the courts' discretion might have been curtailed by the development of case law,[108] with the effect being that grants of injunctions are hardly ever questioned on a principal basis. On the other hand, as already mentioned above,[109] English courts are prepared to look into the principle of proportionality as stemming from the Enforcement Directive in making its decisions.

53. At the same time, the level of rigidity in granting of injunctions might be undergoing a change in respect of injunctions requested in the SEP context. Before the case reached the Commission, Samsung's applications for an injunction have been rejected in the Netherlands, Italy and Spain.[110] Moreover, in *IPCom v Nokia* before the English High Court a request for an injunction was rejected specifically in light of the FRAND commitment and the infringer's willingness to agree a license.[111] Furthermore, it appears that in the UK and in the Netherlands an infringer can avoid an injunction by agreeing to pay a FRAND rate set by the Court (which the Court can provide upon request).[112]

54. So it would seem that if willing to take a more nuanced position, the Member States' (patent) courts are already well prepared to tackle the issue of injunctions in the SEP context. The legislative instruments are already providing adequate mechanisms, the question only relates to the issue of how well they are used in practice. The advantage that the patent courts have in the matter is that they are in a better position to balance

106 The French Intellectual Property Code providing for an ability of the patent holder to exclude others from using the invention is interpreted as conclusive for the courts when granting injunctions.

107 European Observatory on Counterfeiting and Piracy, "Injunctions and Intellectual Property Rights", Report available at http://ec.europa.eu/internal_market/iprenforcement/docs/injunctions_en.pdf (accessed 4 February 2017), p 4 of the Executive Summary.

108 See *Shelfer v City of London Electric Lighting Company* (1895) 1 Ch. 287 (establishing a "good working rule" for when damages should be provided in lieu), recently put into doubt by the Supreme Court in *Coventry and Others v. Lawrence and Another* (2014) UKSC 13 (both are real property cases).

109 Para 49, n 100.

110 Alison Jones (n 46), p 10.

111 ibid, [2012] EWHC 1446 (Ch).

112 Camesasca et al (n 24), p 296.

the interests on a case-by-case basis and decide the issue of granting of injunctions without the threat of an incentive changing fine. The balancing of interests of breakthrough and follow-on innovators is a task with which patent courts are well acquainted with, making it a natural forum for such discussion. They might be considered better suited for that task particularly if the question of FRAND assessment cannot be avoided as part of the examination of the injunction request. Yet, as the *Orange-Book-Standard* line of cases has shown, national courts can take diverging approaches to that balancing task. This actually shows that an injunction can be a "threat only as powerful as the standards for getting an injunction are weak".[113]

55. While the intervention of the Commission in the question of patent injunctions might have been dictated by the inadequacy of the German approach and the fragmentation of the European patent system in general, the approach that the forthcoming Unitary Patent Court (the UPC) might take to the issue of injunctions becomes of interest. Articles 62 and 63 of the Unitary Patent Court Agreement, concerning provisional (i.e.preliminary) injunctions and permanent injunctions respectively, are both expressed in permissive terms (i.e. the Court "may"), as opposed to the wording of article 68 concerning damages, which states that the Court "shall" order the payment of damages in the event of the infringement being found, suggesting that it should be a discretionary remedy. Only article 62 (and not article 63), however, provides that the "Court shall have discretion to weigh up the interests of the parties and in particular to take into account the potential harm for either of the parties resulting from the granting or the refusal of the injunction",[114] thus raising a question how permanent injunctions will be assessed. It appears that it was a contested issue, as suggested by the varying draft versions of the rules of procedure of the UPC.[115] Explanatory Notes to the draft

113 Ginsburg et al (n 99), p 6.

114 Art 62(2).

115 The 16th version of the draft rules of procedure contained a rule 118.2 which stated that: "Without prejudice to the general discretion provided for in Articles 63 and 64 of the Agreement, in appropriate cases and at the request of the party liable to the orders and measures provided for in paragraph 1 the Court may order damages and/or compensation to be paid to the injured party instead of applying the orders and measures if that person acted unintentionally and without negligence, if execution of the orders and measures in question would cause such party disproportionate harm and if damages and/or compensation to the injured party appear to the Court to be reasonably satisfactory." This rule has been removed from the 17th draft and it has not been reinstated in the 18th agreed Rules of Procedure. The simplified rule 118 does not refer to the weighting of harm incurred by the parties, but still speaks of the "discretion of the Court referred to in Articles 63.." Table with explanatory notes to the changes made by the Legal Group of the Preparatory Committee in the 17th draft of the Rules of Procedure of 31 October 2014, available at https://www.unified-patent-court.org/sites/default/files/Digest_Legal_Group_17th_Draft_RoP.PDF (accessed 06 February 2017) sheds some light on the reasons for the change:" The deletion of the wording which stems from Article

rules of Procedure suggest that it is expected that the Court will hardly use its discretion to refuse an injunction where an infringement is shown.[116] It remains to be seen how the UPC will interpret these provisions.

56. By adopting a more nuanced approach to the question of exercising of the discretion to grant an injunction, patent courts might also ease competitive concerns by reacting to the process of atomisation of patent protection. As noted at the outset of this chapter, modern ICT standards are often composed of hundreds if not thousands of patents. Nearly 3000 patents have been declared essential in respect of the 3G standard developed by ETSI.[117] While one solution to that problem would be to change patent granting practices and to reject applications over trivial inventions or applications divided into several independent requests, it would be a long term project, the success of which would likely to be dependent on the resources available to the EPO and the national patent offices. As will be seen below, the US patent courts seem to have found an alternative way of dealing with this problem, by rejecting injunction requests in cases where the patented invention constitutes only a small part of the infringing product.

A view from the other side of the Atlantic

57. The FTC investigated *Google/Motorola*[118] in parallel with the Commission and asserted that the SEP holder's conduct violated section 5 of the FTCA.[119] The FTC's intention to intervene under section 5, which is directed at acts of unfair competition, does not necessarily mean that it regarded this conduct as an antitrust violation. Depending on how widely one interprets this provision, it could be taken to reach beyond other antitrust laws.[120] Thus, the decision could be seen as determining that

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12 of the Enforcement Directive 2004/48/EC is in line with EU law since the directive does not make implementation of this provision an obligation of MS("Member States may provide"). Where the Court finds an infringement of a patent it will under Article 63 of the Agreement give order of injunctive relief. Only under very exceptional circumstances it will use its discretion and not give such an order. This follows from Article 25 of the Agreement which recognizes the right to prevent the use of the invention without the consent of the patent proprietor as the core right of the patentee."

116 ibid.

117 Joaquin Almunia, "Introductory remarks on Motorola and Samsung decisions on standard essential patents" SPEECH/14/345 of 29 April 2014.

118 Motorola was acquired by Google which continued the injunction request practice following the acquisition.

119 It actually was not the first instance in which the FTC challenged SEP holder's use of an injunction, see Bosch merger case: Robert Bosch GmbH, Docket No. C-4377, FTC (26 Nov 2012).

120 See *FTC v. Sperry Hutchinson Co.*, 405 U.S. 233, 234 (1972) and William E Kovacic and Marc Winerman, "Competition Policy and the Application of Section 5 of the Federal Trade Commission

patent hold-up is not an antitrust violation.[121] While this could suggest a very different approach from that taken in the EU, it should not be forgotten that there are significant differences in how the US antitrust system operates. Section 2 of the Sherman Act does not regulate how a monopolist should use their market power, so there is no scope for challenging excessive pricing. It is only when market power is obtained in an anticompetitive way that there is scope for intervention.

58. To an extent, *Google Consent Order* nonetheless remains relevant to the present discussion in so far as the statement of the FTC together with the dissenting statement and the separate statement reveal the reasoning underlying the FTC's approach. It is interesting to see in particular that the FTC viewed Motorola's conduct as a breach of the FRAND commitment. The decisions of the Court of Justice and the Commission fall short of stating that. It was also critical of amassing patents for purely defensive purposes, especially in the standard-setting context, while being positive about the role of the standard-setting itself in promoting innovation (similarly to the European Commission on that latter point). It also noted how the use of section 5 on its own eliminates the risk of treble damages in private suits, a risk that does not exist in parallel in the EU.

59. While the FTC's investigation into Google ended up with a consent order, it allowed the FTC to create a procedural framework imposing specific obligations on Google in a similar way that the Commission did in accepting Samsung's commitments. The European Commission referred to the *Google Consent Order* in its Motorola decision and observed that it was meant to protect not unwilling licensees from SEP-based injunctions and noted that it similarly did not view challenges of validity as signs of unwillingness,[122] but it did not rely on the FTC's approach beyond that.

60. The FTC's approach proved to be controversial in many respects: the dissenting statement concentrates on the ambiguity of the guidance given to market participants and the uncertainty in which it puts the patent holders who cannot be sure if they can safely seek an injunction. The same accusation could be made of the Court of Justice's approach in *Huawei v ZTE*, since the patent holders cannot be sure if they fulfilled their obligations as they turn on the uncertain meaning of FRAND terms – a situation which can have a chilling effect on their incentives. The separate statement, on the

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Act" (2010) 76(3) Antitrust Law Journal 929 for a discussion controversy surrounding the scope of section 5 FTCA.

121 Lundqvist (n 75), p 9.

122 Para 177.

other hand, more clearly considered injunctions to be antithetical to the FRAND commitment and so took an even stronger stance than the FTC statement. The Commissioner who made that statement was of the opinion though that the situation had nothing to do with patent hold up.

61. It is also interesting to see that the FTC decided to intervene despite having a more developed doctrine for granting or refusing an injunction as a matter of patent law, one relying on the principles of equity. Under the Supreme Court's test established in *eBay v MercExchange LLC* it is not altogether easy to obtain an injunction.[123] The Supreme Court ruled in that case that there is no general rule that would favour granting of permanent injunctions after a finding of infringement. Instead, the patent holder must demonstrate cumulatively that: 1) it has suffered irreparable injury, 2) damages would be an inadequate remedy, 3) the public interest would not be disserved by a permanent injunction, and 4) that the remedy is warranted in equity considering the balance of hardships between the plaintiff and the defendant. In establishing these cumulative requirements, the Court could be seen as bringing case law in line with section 283 of the Patent Act, which states that competent courts "*may* grant injunctions in accordance with the *principles of equity* to prevent the violation of any right secured by patent".[124]

62. The latter two requirements of the test established by the Court in *eBay v MercExchange LLC* should be sufficient to address the potential problem of patent hold up. Indeed, the discretionary nature of the remedy puts into doubt the theoretical patent hold up model devised by Shapiro, since it is based on an assumption that an injunction is always available.[125] Considering that the US patent law appears to be well prepared for the balancing exercise between the interests of breakthrough and follow-on innovators in the patent injunction context, it becomes difficult to explain why the FTC felt that it should get involved in the matter. Could there be another reason for its involvement other than insufficiency of patent law solutions or is it just an instance of overzealous enforcement? An answer to that question does not appear immediately from the reasoning of the Google Consent Order.

63. The four step test established in *eBay v MercExchange LLC* had a big impact on the type of cases that can succeed in obtaining an injunction, notably limiting it to those in

123 547 US 388 (2006).
124 35 U.S. Code § 283; emphasis added.
125 Shapiro (n 23).

which the patent holder is also a competitor on the market (the patent holder in *eBay v MercExchange LLC* itself was not practicing its inventions). The rule thus became a measure to deal with so called patent trolls. Some of the lower courts have also supplemented it by a "nexus test" whereby the plaintiff must also establish "that a sufficiently strong causal nexus relates the alleged harm to the alleged infringement."[126] In this way the courts manage to address a situation in which the patented invention constitutes only a very small part of the finished product, as it often happens in the ICT industry. To obtain an injunction the patent holder must show that the infringing feature drives consumer demand for the accused product. Thus achieved balancing of the interests of breakthrough and follow-on innovators ensures that injunctions are granted only where the patent holder's interests going beyond not obtaining their royalties might be hurt as a result of the infringement.

VI Conclusions

64. The analysis above has shown that an approach of the Commission and the Court of Justice to the issue of the use of injunctions in the SEP context proved to be another matter that can be seen as problematic in terms of balancing of antitrust and patent policy interests as viewed from the innovation perspective. Although the innovation dimension of the cases decided by the Commission and referred to the Court of Justice is pretty obvious, little attempt has been made to include it in the analysis of the issues at stake. Both the Commission and the Court of Justice recognised the role that standards can play in encouraging innovation and the role of patent rights as an inventive effort rewarding mechanism that equally supports innovativeness. This awareness did not, however, translate to any serious consideration of the effects of the finding of an antitrust infringement on those values. The problems encountered by the Commission and the CJEU in respect of the pharmaceutical cases discussed in the previous chapters cannot be thus seen as an issue that is industry-specific.

65. The criticism to be made in respect of the SEP decisions is not simply that the risk of reverse patent hold up was undervalued in the balancing exercise to be had, but that it did not enter the deliberation process at all. While the Commission addressed the issue of SEP injunctions through the theory of harm centring on patent hold up, making the

126 *Malibu Boats LLC v Nautique Boat Co, Inc* (2014) 997 F Supp 2d 866, 885, relying on *Apple Inc. v. Samsung Elec. Co., Ltd. (Apple II)*, (2012) 695 F 3d 1370, 1374.

corresponding lack of consideration of reverse hold up even more stunning, the Court of Justice did not even phrase its decision in terms of patent hold up despite this being the way the issue was portrayed by the referring court. Could this suggest that the Court was not prepared to engage with the theoretical underpinnings of the precedent it set? If the harm done is simply contained in the fact that the patent holder breached its commitment to license its patent on FRAND terms, then surely alternative contractual or equity methods of dealing with this problem should be sufficient.

66. Unquestionably, availability of other remedies does not preclude antitrust involvement, yet it does not necessarily make it desirable, particularly since the threat of liability and fines may affect the bargaining positions of the parties (an aspect that has not been considered by either the Court or the Commission). In that sense, antitrust law is again put in a position of a repair-it-all mechanism that corrects what is perceived to be inadequate balancing on the part of patent courts (pro-patent bias). While in Europe this could be attempted to be explained by the discrepancy of the approaches of the national patent courts to the issuing of injunctions and the corresponding lack of belief on the part of the competition authorities in their ability to handle this problem, adequacy of the patent solution did not stop the FTC from finding SEP injunctions suspicious (although not strictly on antitrust grounds).

67. The replacement of the economic analysis aimed at the examination of the parties' incentives and the effects of a particular position on the innovation process with the formalistic analysis grounded in fundamental rights is unfortunate. The balancing of rights performed under this standard appears rather superficial and legalistic, since it seems to be aimed at securing legitimacy more than anything else. While the phrasing of the issue in terms of rights could serve to highlight the importance of patent rights, the opposite seems to have been achieved, especially in the analysis performed by the Commission. If anything, the cases discussed above seem to further confirm a claim of a potential of bias against patents.

68. When remarking upon the potential for anti-patent bias, one cannot help but wonder whether the differing outcomes reached by the Commission and the Court of Justice could possibly be a result of their differing roles and institutional set up – in particular whether the Commission's prosecutorial role in issuing a prohibition decision could have influenced the outcome and whether it could be contrasted with the position of the Court which presumably can deliberate more freely when giving preliminary ruling decisions? While the differing outcomes of the SEP injunction cases could give

rise to such supposition, it appears too hasty to reach such a bold conclusion on the basis of a single case. It would, however, go in line with the argument that specialised administrative bodies are more exposed to the risk of bias than more generalist courts.[127]

69. Last but not least, some similarities and differences of these cases with other cases and issues discussed as part of this project should be noted. While the issue of SEP injunctions is in many respects reminiscent of the *Microsoft* case and the refusals to supply, the Court of Justice clearly noted the limited applicability of that case law to the issue at hand, and rightly so. It is also noteworthy to acknowledge that perhaps unlike the other case studies discussed in previous chapters the issue of SEP injunctions does not raise problems in terms of balancing of diverging interests of dynamic efficiency with short term goals. While the Commission's *Motorola* decision touches on the argument that patent hold up might lead to higher prices, it is definitely not a prominent feature of the analysis and not one that would point in a different direction than the one based on innovation. Overall, in the SEP injunction scenario it is rather the innovation requirements that might be pointing in different directions in respect of the upstream and downstream markets that need to be properly balanced.

70. Table 1 below summarises some of the main features of the decisions discussed above for ease of reference in the discussion that will follow.

71.

	Motorola	***Samsung***	***Huawei v ZTE***
Conduct potentially anticompetitive?	✓ (strong pro-infringer position)	✓ (strong pro-infringer position)	✓ (trying to achieve a middle position, could be still problematic for the patent holder)
Basis of intervention	Exceptional circumstances/ competition on the merits	Exceptional circumstances	Exceptional circumstances/ recourse to methods other than normal competition

[127] See further ch 9 to that effect.

Theory of harm	Exclusion/ inducing the infringer to accept disadvantageous terms	Exclusion/ inducing the infringer to accept disadvantageous terms	? FRAND commitment creates legitimate expectations that SEP will be licensed on those terms
Created a framework for the parties to follow?	×	✓	✓
Innovation aspect entering the analysis	✓/× (in respect of non-challenge clauses)	×	×
Economic analysis	✓/×	×	×
Fundamental rights analysis	✓	✓	✓
Discussion of reverse hold-up	× (rejected on the facts, not discussed as a matter of principle)	×	×
Other important features	Emphasis on non-challenge clauses Failed efficiency defence Mixed industry context sensitivity		Refusals to supply case law only partially applicable

Table 1 Main features of SEP injunction decisions before the EU authorities.

Chapter 7

A long forgotten tale of *ITT Promedia* and the issue of vexatious litigation

I Introduction

1. The case-studies examined in the previous chapters can all be linked to patent litigation. Equally, the Pharmaceutical Sector Inquiry also reviewed the issue of patent litigation and the effects it can have on potential competitors of the patent holder, be it generic producers or other originators. Although the cases of patent misuse discussed so far could perhaps be analysed within the framework of vexatious litigation, the EU competition authorities refrained from doing so. The *ITT Promedia*,[1] as confirmed by *Protégé*,[2] remains the only case in which vexatious litigation was considered to come within the scope of competition law.
2. The high-threshold for liability established by the EU competition authorities in this area could be reflective of the recognition of the importance of the right of access to justice which significantly curtails the scope for finding an anticompetitive action in respect of litigation activity. However, it can also be said to be illustrative of the regulatory choice not to get involved in patent matters in this respect. While, admittedly, the problem of vexatious litigation is not specific to patent litigation, in the patent context it takes on a particular importance. Sham or vexatious patent litigation, could lead to an "over-enforcement" which could have a deterrent effect on competitors, and thus also on the level innovative activity (by removing competitors as a source of further innovative activity and as a source of competitive pressure on the original innovator to continue innovating). Equally though, the value of the patent goes only so far as it is possible to enforce that right. Access to courts forms an integral part of the subject-matter of the patent.[3] Thus, access to courts is significant not only in its own right as a fundamental right,[4] but also from the patent perspective. Any signal to the effect that patent holders need to be wary of enforcing their patents

1 Case T-111/96 *ITT Promedia NV v Commission* [1998] ECR II-2937.

2 Case T-119/09 *Protégé International Ltd v European Commission and Pernod Ricard SA* ECLI:EU:T:2012:421*;* the case did not concern the use of exclusive rights.

3 The fact that access to the courts forms part of the subject-matter of the patent has been recognised by the Commission in Case AT.39612 *Perindopril (Servier)* C(2014)4955 final, para 1196.

4 As enshrined in art 47 of the Charter and art 6(1) of the ECHR.

for fear of antitrust liability could have a chilling effect on innovation by diminishing the value of the patent right as a rewarding mechanism.

3. The possibility of framing of the case studies discussed in this thesis as problems of vexatious litigation is significant for several reasons. Firstly, it asks about the relationship between different strands of case law and begs a question whether there exists some overarching standard for deciding whether an antitrust intervention is warranted. Conversely, if such overarching standard does not exist, then it might still serve as an aid in identifying differences between the issues discussed here. It might help explaining why the Commission is prepared to take an interventionist stance in one area, while remaining rather deferential in another. Moreover, a comparison with the issue of vexatious litigation might be read as an invitation to consider the balancing of interests at play by giving greater focus to the question of access to justice understood as part of the subject-matter of a patent right. Finally, framing those issues as those of vexatious or 'wrongful' litigation opens the doors to considering patent law or general law solutions to the problem instead of antitrust enforcement. All in all, the court that hears the original case as it arose might be better suited to assess whether an abuse of process has taken place. Indeed, previous practice suggests that issues of vexatious litigation are more likely to be assessed at a national level rather than through EU antitrust law under which there is no case finding an infringement under this ground.

4. This chapter commences with an account of the approach of the EU competition authorities to vexatious litigation as established in the *ITT Promedia* case. It also considers the suggestions made in that context in the Sector Inquiry and the IP side of the issue (section II). It then continues to see how, if at all, the *ITT Promedia* approach was considered in the cases discussed in this Part of the paper - *AstraZeneca*, *Motorola*, *Huawei v ZTE*, *Lundbeck* and *Servier* (section III). In this way the case studies forming the subject matter of this part of the project are tied together. A comparison is then made with the US practice in this area, which in some respects shows close similarities, and in some diverges from the European practice (section IV).

II A European approach to vexatious litigation

ITT Promedia

5. The *ITT Promedia* principle arises out of a Commission decision in which it rejected a complaint that a Belgian telephone operator Belgacom abused its dominant position *inter alia* by commencing vexatious litigation against the complainant, ITT Promedia who had previously had exclusive rights to publish telephone directories in Belgium.[5] While the Commission conceded that vexatious litigation could constitute abuse of a dominant position, it rejected the claim at hand. In doing so, it established two cumulative criteria for finding abuse: first, the action could not reasonably be considered an attempt to establish rights of the undertaking concerned and could therefore only serve to harass the opposite party and second, it would need to be conceived in the framework of a plan whose goal is to eliminate competition.

6. The decision was appealed to the Court of Justice (CFI), which upheld the Commission decision, but while it applied the Commission's test,[6] it did not rule on the correctness of the cumulative criteria,[7] since the appeal concerned manifest error of assessment and so did not challenge the compatibility of the criteria with article 86 EC.[8] Subsequently, the test has been endorsed in *Protégé*,[9] another decision affirming the Commission's margin of discretion in rejecting a complaint.

7. The two prong test establishes a high threshold for finding an abuse resulting from vexatious litigation, since it must be established that harassment was the *sole* purpose of the action and that it was the defendant's intention to eliminate competition (subjective element). To date, there are no decisions or cases finding an abuse under this test. Although there might be good reasons for establishing the threshold so high, not least those connected to the right of access to justice, it could be argued that the Commission has effectively closed the doors for prosecuting cases of vexatious litigation under competition law by modelling the test in this way. The apparent reluctance to engage in the issues of 'wrongful' litigation could perhaps be contrasted with the ostensible interest of the Commission in those matters as part of the Pharmaceutical Sector inquiry.

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5 Since Belgacom was state-owned, it was an art 86 EC (now art 106 TFEU) case.

6 Only the first prong of the test – the Court declined to apply the second prong, since the first prong of the test was not met.

7 Para 58.

8 Paras 52 and 57.

9 The case did not concern the use of exclusive rights.

Sector inquiry

8. As it was already discussed in chapter 5, the Pharmaceutical Sector Inquiry Report does not contain guidance on the compatibility of the practices it discusses with competition law. It is evident though, that it views some litigation strategies employed by the patent holders in the pharmaceutical sector as potentially problematic. The Report underlines how litigation or even a threat thereof can deter entry, in particular of smaller companies fearing the cost of litigation.[10] It lists litigation as one of the strategies employed by the patent holders and notes that in certain circumstances "originator companies may consider litigation not so much on the merits, but rather as a signal to deter generic entrants".[11] It is not clear, however, whether the Commission would be prepared to prosecute such cases beyond the scope of the limit established by the *ITT Promedia* case or indeed whether it considers that the problems identified in the Report should be addressed through antitrust law.

An intellectual property approach

9. TRIPS agreement imposes upon its members an obligation to ensure that enforcement procedures against intellectual property infringement are applied in such a manner as to provide for safeguards against their abuse.[12] In the same vein, article 3(2) of the Enforcement Directive contains the same requirement.[13] Since neither of those require establishing separate procedures for IP enforcement,[14] many Member States address the issue of abuse through general law. Hence, for example, in the UK vexatious litigation can be addressed through a common law tort of an abuse of process.[15] At the same time, the Patents Act 1977 supplements common law by providing specific provisions that make it an offence to issue groundless threats of legal proceedings

10 See in particular, Pharmaceutical Sector Inquiry Final Report, paras 542-550.
11 ibid, para 549.
12 Art 41(1) TRIPS.
13 Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights [2004] OJ L 195/16.
14 Indeed, art 41(5) TRIPS expressly clarifies that.
15 See *Grainger v Hill* (1838) 4 Bing NC 212, 132 ER 769; *Varawa v Howard Smith Co Ltd* (1911) 13 CLR 35; *Metall und Rohstoff AG v Donaldson Lufkin& Jenrette Inc* [1990] 1 QB 391, [1989] 3 All ER 14; see further *Crawford Adjusters v Sagicor General Insurance (Cayman) Ltd* [2013] UKPC 17; [2013] 3 WLR 927 (PC (CI)) as discussed by Tom K.C. Ng, "The torts of malicious prosecution and abuse of legal process" (2014) 130 (Jan) LQR 43-47 on the relationship between abuse of process and malicious prosecution.

under certain circumstances.[16] The issue of groundless threats of litigation is closely connected to that of vexatious litigation and although the *ITT Promedia* principle does not expressly refer to threats of litigation, it would appear that they could be equally anticompetitive, since they could have the same effect of deterring entry, as was indeed recognised in the Sector Inquiry Report.[17] In other Member States, such as Germany, France or the Netherlands, unjustified threats are also addressed through general tort provisions.[18]

10. Coming back to the UK jurisdiction, it is also an interesting example because prior to the *ITT Promedia*, the position of the English High Court was that vexatious litigation does not constitute an abuse of a dominant position. In *Pitney Bowes Inc v Francotyp-Postalia GmbH*, a patent infringement action, Hoffman J. (as he then was) stated in very colourful words that:

> For a dominant supplier to arrange to have a competitor's factory blow up is a tort and may well strengthen its dominant position, but I do not see how it can be called an abuse of his dominant position. The same is true of other torts such as malicious prosecution.[19]

It was thus considered that an allegation of vexatious litigation could not be used as a counterclaim in a patent infringement action as an abuse under article 86 of the Treaty of Rome (now article 102 TFEU). In the opinion of the Court antitrust liability should not be applied to every situation in which the undertaking's dominant position is strengthened, even if that results from a commission of a recognised tort. In effect, the apparent sufficiency of domestic remedies – availability of torts of an abuse of process and/or malicious prosecution – ruled out availability of an antitrust remedy. This is in contrast with the position under EU law, which does not preclude the use of antitrust simply because a remedy under another branch of law exists.

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16 S 70. Groundless threats of patent litigation are not a tort at common law (*Halsey v Brotherhood* (1881-82) LR 19 Ch 386). The provisions on unjustified threats of IP litigation have been recently reviewed by the Law Commission of England and Wales. The report arising out of the public consultation confirmed the need to retain those provisions, but suggested some reforms: The Law Commission, "Patents, Trade Marks and Design Rights: Groundless Threats" (2014) Law Commission Report No 346; The Law Commission, "Patents, Trade Marks and Designs: Unjustified Threats" (2015) Law Commission Report No 360.

17 Paras 544 and 575.

18 See Law Commission, "Patents, Trade Marks and Design Rights: Groundless Threats" (2013) Consultation Paper No 212, paras 6.20-6.6.36.

19 [1991] FSR 72 (ChD), [1990] 3 CMLR 466, para 17.

11. The position taken by Hoffman J. has been criticised on the ground that it failed to take into consideration the competitive impact of the alleged conduct, regardless of its tortious status, it being a *sui generis* separate mischief at stake.[20] Nonetheless, the position taken by Hoffman J. in *Pitney Bowes* constituted an alternative regulatory choice, whereby antitrust law was not to be used as a repair-it-all mechanism. It could also be reflective of the delicacy of the issue at play and the fact that antitrust could constitute a crude remedy or, more likely, be a reflection of a traditional mistrust towards 'Euro-defences' in English law.[21]

III *ITT Promedia* not taken up in other patent misuse cases

Smartphone wars

12. The litigation war between Apple and Samsung extended to numerous suits conducted on four continents that cost over a billion dollars and attracted not only the attention of lawyers but also of the public at large.[22] As the smartphone war ensued there were hints here and there that the ongoing litigation is more of a "ruthless business tactic" rather than arising out of a genuine concern over the effects of patent infringement.[23] Yet, the issue as it was analysed before the courts was not one of vexatious litigation. This is presumably because a claim that the actions were obviously unmeritorious could not be sustained in light of the rich patent portfolio owned by Samsung and the indispensability of the patents it owned. Thus, the objective part of the assessment under the *ITT Promedia* test could not possibly be met, even if the actions were to be shown to be brought in bad faith.

13. In consequence, the way smartphone wars were approached by the Commission was to limit the ability to request a particular remedy in the specific SEP context. Since this way of solving the problem also entailed the question of right of access to justice and cut the availability of litigious action, it raised questions about the correspondence of the standard of liability established there with that of *ITT Promedia*. Indeed, it has

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20 Steven Preece, "ITT Promedia v E.C. Commission: establishing an abuse of predatory litigation?" (1999) 20(2) European Competition Law Review 118, pp 120-121.

21 See Okeoghene Odudu, "Competition Law and Contract: the Euro-defence" in Dorota Leczykiewicz and Stephen Weatherill (eds), *The involvement of EU law in private law relationships* (Hart Publishing Limited 2013).

22 Vanity Fair, The Great Smartphone War (3rd May 2014), available at http://www.vanityfair.com/news/business/2014/06/apple-samsung-smartphone-patent-war (accessed 20 April 2016).

23 ibid.

been argued by Motorola that its conduct could constitute abuse only in the wholly exceptional circumstances, i.e. if the two cumulative criteria from *ITT Promedia* were met. It further argued that these should be construed and applied strictly as "an exception to the general principle of access to the courts".[24]

14. The Commission, however, distanced itself from the *ITT Promedia* ruling by arguing that the Court in that case has not established a "different legal standard to the one developed by the case-law of the Court of Justice with regard to the type of restrictions that may be imposed under Union law on the right of access to a court."[25] The Commission further relied on the *IMS Health* case[26] as an example where an abuse was found outside the *ITT Promedia* criteria to conclude that *ITT Promedia* did not limit the circumstances under which an abuse under article 102 can be found in the IPR context. Moreover, the Commission differentiated the case at hand from the *ITT Promedia* on the basis of the particular SEP FRAND circumstances.[27] It thus considered that the circumstances giving rise to abuse in the *Motorola* decision were separate from the ones in *ITT Promedia*. Since it was considered a separate form of abuse, it was not justified as an extension and thus a re-balancing of the vexatious litigation principle, even though it could be portrayed as such. In effect, the Commission (and later also the Court in *Huawei v ZTE*) addressed another form of 'wrongful' litigation outside the remit of the principle of vexatious litigation as established in *ITT Promedia*.

A connection to reverse payment settlements?

15. It could be said that the connection of the reverse payment settlement decisions discussed in chapter 3 with the issue of vexatious litigation is slim or perhaps even non-existent. Yet, when faced with the problem of reverse payment settlements, Chief Justice Roberts, who gave a dissenting opinion in *Actavis*,[28] took the position that these agreements should attract antitrust scrutiny only if the underlying litigation was a sham or a result of enforcement of a patent obtained by fraud. In this respect the dissenting opinion mirrored the stance taken by the 2nd circuit court in *In re*

24 Case AT.39985 - *Motorola - Enforcement of GPRS Standard Essential Patents*, C(2014)2892 final, para 527.
25 ibid, para 531.
26 Case C-418/01 *IMS Health GmbH & Co. OHG v NDC Health GmbH & Co. KG* [2004] ECR I-5039.
27 *Motorola* (n 24),paras 532-533.
28 *FTC v Actavis, Inc., et al.* 133 S.Ct. 2223 (2013).

Tamaxifen[29] that predated the US Supreme Court decision on the point. Thus, a linkage between vexatious litigation and treatment of reverse payment settlements is not unheard of.

16. While this approach has not been taken up by the European Commission, one feature of the *Servier* decision bears a hint that Servier's litigation strategy was considered wrongful by the Commission. In that decision, the Commission is evidently sceptical of Servier's enforcement of the '947 patent. It underlined that the ultimate objective of enforcing that patent was to delay generic entry, an aim visible through statements made by Servier following its annulment: "4 years gained = great success".[30] Still, the "investigation has not found any direct evidence that Servier internally considered the '947 patent invalid when filing the patent application."[31] Consequently, the Commission asserted that it has never contested the legitimacy of Servier's infringement suits.[32] In fact, English Court of Appeals in assessing the validity of the said patent stated that nothing that Servier did in enforcing the patent was unlawful and "[t]he only sanction (apart perhaps, from competition law which thus far has had nothing or virtually nothing to say about unmeritorious patents) may [...] lie in an award of costs on the higher (indemnity) scale if the patent is defended unreasonably."[33] This statement was made by Justice Jacob despite the fact that he considered the patent "plainly" invalid and indeed "the sort of patent which can give the patent system a bad name."[34] A limited scope for antitrust intervention based on wrongfulness of enforcement did not, however, stop the Commission from using the perceived wrongfulness of using the patent in the overall assessment of Servier's strategy.

17. Furthermore, the issue of reverse payment settlements raises a question of what is actually meant by the term 'vexatious litigation'. So far, following the example of *ITT Promedia,* this chapter considered vexatious litigation as one which is objectively unmeritorious and instituted with a sole intention to harass and eliminate competition. However, could it be taken to extend to conduct that is sham litigation between

29 *In re Tamoxifen Citrate Antitrust Litig.*, 429 F.3d 370 (2d Cir. 2005).
30 *Servier* (n 3), para 2984.
31 ibid, para 127.
32 ibid, fn 1568.
33 *Les Laboratoires Servier, Servier Laboratories Limited v. Apotex Inc, Apotex Pharmachem Inc, Apotex Europe Limited, Apotex UK Limited* [2008] EWCA Civ 445, para 10.
34 ibid, para 9.

competitors intended to cover collusive practices?[35] Such portrayal of the issue of reverse payment settlements could perhaps allow for a single set of circumstances in which patents' enforcement could be considered anticompetitive. Indeed, the parties in *Servier* argued that antitrust liability should not attach to patent settlement agreements save for the cases in which (a) patent has been obtained by fraud, (b) settled litigation was fictitious or vexatious, or (c) settlement terms go beyond the scope of the patent.[36] Presumably though the meaning ascribed to vexatious litigation under this test was understood by the parties to cover only unmeritorious or sham litigation, especially since they further claimed that it would be consistent with the US case-law.[37]

18. Whichever it may be though, the test has been rejected by the Commission. Unfortunately, in doing so, the Commission did not concentrate on the correlation between its definition of abuse and vexatious litigation, but rather focussed on the scope of the patent element of the proposed test.[38] Still, it offered also some general observations on the proposed test and on the specific aspect of access to court. On the general level, it considered the test too restrictive.[39] On the issue of access to court, it rejected the parties' argument on the basis that the fundamental right of access to courts does not encompass the entitlement to conclude agreements between the parties which restrict competition.[40] In effect, it considered access to justice only as a fundamental right and not as part of the subject-matter of the patent, even though it recognised that latter aspect of access to courts only a few paragraphs above.[41] Moreover, in this way it failed to recognise the gist of the argument, which is that its test might affect legitimate agreements, not only those that restrict competition (i.e. that the test is too broad)[42]. Rather than engaging with the balancing exercise directed at establishing a test that weeds out anticompetitive agreements, but at the same time does not unduly affect the incentives to litigate or to settle, the Commission denied that the issue of access to courts is at play altogether. A recognition of the need of a

35 This is considered to be a form of sham litigation apart from frivolous actions in the IPEA report prepared for WIPO: Committee on Development and Intellectual Property (CDIP), "Study on the Anti-Competitive Enforcement of Intellectual Property Rights: Sham Litigation, prepared by the Institute for Applied Economic Research (IPEA), Brasilia" (June 2012) CDIP/9/INF/6 REV.

36 *Servier* (n 3), para 1192.

37 ibid, para 1199; for the details on the US practice see section IV and para 28 of ch 3.

38 ibid, para 1193 ff.

39 ibid, para 1198.

40 ibid, para 1200.

41 ibid, para 1196.

42 ibid, para 1200.

balancing exercise would in turn allow for drawing a correlation with the issue of vexatious litigation.

AstraZeneca

19. Although not considering litigation per se, since the abuse was held to arise even before patent enforcement, the issue of the relationship with *ITT Promedia* was also raised in the *AstraZeneca* case. AstraZeneca argued, in a similar way to Motorola, that an abuse could only be found if the patent was enforced and then only if the cumulative criteria from *ITT Promedia* were met.[43] However, since the abuse was held not to be limited to enforcement and arise beforehand, the vexatious litigation criteria have been held to be irrelevant by the General Court.[44] In this way the Court avoided discussing the correlation between the two. The Advocate General similarly considered the criteria irrelevant and even considered them speculative in light of the fact that the Court in *ITT Promedia* has not ruled on them.[45] Still, he went a bit further and stated that no meaningful parallel could be drawn between vexatious litigation and regulatory abuse cases like the one presented by *AstraZeneca*. He considered that in the latter case there is no need to preserve the fundamental right of access to justice and thus it was not necessary for the enforcement to be equally restrained, also in light of the highly misleading representations made by the appellant to the patent authorities. This is informative because it shows that the Advocate General considered restraint exercised in respect of vexatious litigation to be caused solely by the need to preserve access to justice in its own right and not by the need to preserve the patent system. In this way, the Advocate General's reasoning resembles that of the Commission in *Servier*. Furthermore, it could also suggest that threats of litigation could be treated differently than vexatious litigation, since they occur before litigation.

20. The Commission in its decision also referred to the *ITT Promedia* in respect of the position of AstraZeneca as a defendant in actions trying to establish invalidity of the SPC protection it improperly gained. The Commission considered that, contrary to AstraZeneca's claim, the Commission in that case has not concluded that defensive conduct cannot be an abuse, but only that such conduct by itself cannot constitute a plan to eliminate competition – in contrast with the position of AstraZeneca whose

43 Case T-321/05 *AstraZeneca v Commission* [2010] ECR II-2805, para 311.

44 ibid, para 363.

45 Para 52 of the AG's Opinion, Case C-457/10 P *Astra Zeneca AB and AstraZeneca plc v European Commission*, ECLI:EU:C:2012:770.

conduct was assessed as part of implementation of such a plan.[46] Admittedly, AstraZeneca's defensive misrepresentations would not have arisen but for the earlier misleading activity which led to the defensive action. It would thus seem that the Commission denied AstraZeneca the right to access to justice when the use of litigation, even if defensive, arose out of an earlier unlawful conduct. Insofar as that earlier conduct meant that the claim was objectively unmeritorious, it would bring this situation closer to the issue of vexatious litigation. The intentional element need not, however, be established under the *AstraZeneca* head of abuse.

IV US practice

21. An issue of the relationship between vexatious litigation and *AstraZeneca* type of abuse brings to mind the discussion of that issue as a matter of US case practice. Similarly to the European practice, under US case-law sham litigation can be similarly anticompetitive. *PREI* judgment establishes a two prong test,[47] similar to the one in *ITT Promedia* to overcome the application of the Noerr-Pennington doctrine establishing immunity from antitrust liability for litigation.[48] First, the lawsuit "must be objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits" and second, a court must also examine whether the "lawsuit conceals an attempt to interfere directly with the business relationships of a competitor" through the "use [of] the governmental process – as opposed to the outcome of that process – as an anticompetitive weapon." Thus, just as in case *of ITT Promedia*, the test consists of both an objective and a subjective element, both of which must be met in order for the exception to apply. In the US, however, the satisfaction of the cumulative criteria does not automatically lead to antitrust liability, but only to the disapplication of the Noerr-Pennington doctrine – the substantive

46 Commission Decision Case COMP/A.37.507/F3 *AstraZeneca* C(2005)1757 final of 15 June 2005, para 737.

47 *Professional Real Estate Investors, Inc v Columbia Pictures Industries, Inc*, 508 U.S. 49 (1993), 60-61.

48 The Noerr-Pennington doctrine takes its name from two cases*: E.R.R. Presidents Conference v Noerr Motor Freight, Inc.*, 365 U.S. 127 (1961) and *United Mine Workers of America v Pennington*, 381 U.S. 657 (1965), the former establishing immunity from antitrust liability for petitioning legislative action, the latter extending the doctrine to attempts to influence the executive branch. The doctrine was later extended also to the judicial context in *California Motor Transport Co. v. Trucking Unlimited*, 404 U.S. 508 (1972).

elements of antitrust liability must be established separately.[49] It appears that to date no case has succeeded in establishing antitrust liability under this head in connection to patent litigation, although the issue of sham litigation is often raised as a defence in patent infringement actions.[50]

22. It appears also that in establishing the contours of liability for sham litigation, the US courts were not solely concerned about the proper balance with the first amendment rights as protected by the Noerr-Pennington doctrine. In *Handgards*,[51] a case predating *PREI* which was the first one to hold that a patent infringement lawsuit may be the basis of antitrust liability, the Ninth Circuit was minded to observe that "undue readiness to hold an infringement suit improper would diminish the protection afforded by patent grants, contrary to their purpose."[52] This commendable approach stands in contrast with the understanding of the significance of access to courts in the patent context displayed in *Servier* and *AstraZeneca*.

23. While the *PREI* decision establishes that sham litigation may be anticompetitive, the *Walker Process* case, discussed already in chapter 4, establishes that enforcing a patent obtained by fraud may be anticompetitive under section 2 of the Sherman Act. As it has been already discussed, the *Walker Process* doctrine, which is the closest equivalent of the abuse found in *AstraZeneca*, imposes more stringent requirements for establishing liability than that latter European case.[53] The relationship between the *Walker Process* case and sham litigation, as articulated in *PREI*, has been discussed in the *Nobelpharma* case.[54] Essentially, the court considered that the two cases provide alternative grounds for stripping patentee of its immunity and that both can be applied to the same conduct.[55] Yet, the two situations might be closely connected: if it is shown that the patent has been obtained by fraud, then the unreasonableness of the infringement (so the first prong of the sham litigation test from *PREI*) is then

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49 *PREI* (n 47), at 60; see further Gary Myers, "Antitrust and First Amendment Implications of Professional Real Estate Investors" (1994) 51(4) Washington and Lee Law Review 1198 for a detailed account of the case.

50 IPEA Report (n 35), p 20; the FTC alleged that Bristol-Myers Squibb Corporation filed baseless patent infringement suits in *In the Matter of Bristol-Myers Squibb Company* (Docket No. C-4076), a pharmaceutical case concerning delay of generic entry, but the case was settled: https://www.ftc.gov/enforcement/cases-proceedings/0110046/bristol-myers-squibb-company-matter (accessed 20 April 2016).

51 *Handgards, Inc v Ethicon, Inc (Handgards I)*, 601 F.2nd 986 (9th Cir.1979).

52 Herbert J Hovenkamp, "The Walker Process Doctrine: Infringement Lawsuits as Antitrust Violations" (2008) University of Iowa Legal Studies Research Paper Number 08-36, pp 24-25.

53 By requiring evidence of fraud, for more details see ch 4, para 36 ff.

54 *Nobelpharma AB v Implant Innovations*, 141 f.3d 1059 (Fed. Cir.) cert. denied 525 US 876 (1998).

55 ibid, at 48.

automatically established.[56] Still, the inequitable conduct required for establishing that litigation was sham is a much wider and more inclusive concept that might concern a number of circumstances not necessarily connected to patent filing.[57] Contrary to the European approach, under the US law it is the misuse of the patent system under the *Walker Process* principle which establishes the higher threshold for antitrust involvement, since reliance on the standard of fraud requires proof of intent and materiality.[58]

24. Even though the court in *Nobelpharma* did not consider it necessary to merge the two separate lines of cases, it can be read as an attempt to establish coherence in the case-law on antitrust involvement in patent issues.[59] The same coherence, however, is not visible in the European cases. The cases discussed in this chapter also developed each as establishing a separate line of abuse. In that sense they are no different from the US approach. However, there appears to be a dissonance in the level of deference afforded to the question of access to courts as part of the subject-matter of the patent and the corresponding effects of the decisions on the incentives to litigate or settle in the case-law, despite all the cases having that aspect in common. While neither the Commission nor the Court of Justice are formally required to draw comparisons between different lines of cases and all cases are technically decided under the same standard of article 102, the approach to vexatious litigation seems to stand in stark contrast with the approach in other areas discussed above. This difference might be justified by the particular circumstances, however, it is hard to pin point exactly what it is that makes those cases different in absence of a clear explanation from the authorities.

V Conclusions

25. All of the competition law decisions discussed in this Part more or less directly concern the anticompetitiveness of conduct in the patent litigation context. Thus, the question of balancing of access to courts against a possible finding of anticompetitiveness – an issue vital for the patent value as a rewarding mechanism and

56 Hovenkamp (n 52), p 12.
57 *Nobelpharma* (n 54), at 41 and 51; Hovenkamp (n 52), p 11.
58 *Nobelpharma* (n 54), at 47.
59 Deidre L Conley, "Nobelpharma AB v Implant Innovations, Inc." (1999) 14(1) Berkley Technology Law Journal 209, p 226.

so from the innovation perspective – is an important aspect in all of the cases discussed. It is a common thread that ties those issues together. Yet, the cases developed each on its own without parallels drawn by the competition authorities between different lines of cases. When compared with the issue of vexatious litigation, an approach to which was established over two decades ago in the *ITT Promedia* case, the newer decisions appear to represent a different, more intrusive approach towards issues arising at the antitrust-patent intersection. Yet, there is no suggestion that *ITT Promedia* is no longer good law. Indeed, the high threshold to be applied to vexatious litigation has been confirmed relatively recently in *Protégé.*

26. It might be that those decisions simply represent a different set of circumstances, rather than a different approach. In fact, we do not have enough information to know what was the underlying reasoning that informed the outcome of the *ITT Promedia* case, since it is a relatively short decision in which the appropriateness of the test proposed by the Commission has not been challenged – perhaps it was the unwillingness of the Commission to take up that particular case or deference to the right of access to justice understood as a fundamental right that led to the formulation of the test in this particular way.

27. While the approach to vexatious litigation appears to represent a more deferential approach to patent issues with reliance put more clearly on the patent system or general law solutions and little space for antitrust involvement, it is not surprising that the parties in other cases tried to rely on that standard. In this way they provided an opportunity for the competition authorities to justify their course of action. The challenges to the appropriateness of the tests applied in decisions like *Servier* or *AstraZeneca* advanced by reference to the vexatious litigation standard raised at their heart the question of the risk of antitrust over-enforcement (type I errors). In addition, they invited the Commission to consider access to courts not solely as a fundamental right, but also as part of the subject-matter of the patent. Yet, the invitation to expand on the issue of the correlation between different lines of cases has not been taken up by the Commission in the way it was done in the US *Nobelpharma* case. Perhaps, this is because the cases as they developed in Europe do not represent the same level of coherence.

Chapter 8

Observations to be drawn from the case studies

1. Before moving on to the next Part, this chapter shortly summarises the common themes that can be observed in the case studies explored in the chapters of this Part (chapters 3-7). It also contains a short section comparing the treatment of the innovation dimension in antitrust analysis as scrutinised in the rest of this thesis with that in EU merger analysis.

I A pro interventionist stance...

2. In deciding to intervene in the cases described in this Part, antitrust authorities might be said to have taken an interventionist stance to issues arising in the patent context. The Commission and the Court were not deterred by arguments that those issues are falling within the competence of patent authorities or cannot be possibly considered anticompetitive because of the patent context. In deciding to get involved in patent matters the Commission and the Court of Justice used various tests to describe the limits/provide a justification for antitrust intervention. In respect of reverse payment settlements, the tests used were based on the subject-matter of the patent and a distinction between existence and exercise of patents. At the same time the Court in *Lundbeck* rejected a test based on the scope of the patent (like its US counterpart in *Actavis*) and a suggestion that antitrust applied to patent matters in the context of article 101(1) only in the exceptional circumstances. In the context of an application of article 102 as seen in *AstraZeneca* and standard essential patents (SEP) cases, on the other hand, the standard of 'competition on the merits' (*Astrazeneca*) and 'recourse to methods of other than normal competition' was used as well as the 'exceptional circumstances' test (SEP cases). There thus appears to be no overarching standard that would apply to all patent cases arising in the antitrust context. All that is clear is that patent holders do not enjoy an immunity in respect of patent related activity, while at the same time there are some limits to antitrust intervention.

3. While the tests applied by the European competition authorities will be discussed in more detail in Part III,[1] for now it needs to be recognised that the intensity of intervention does not rely on the application of those tests, which can be interpreted in many ways, but rather on the framing of the issues at hand. Chapter 7 has shown that all those issues could be characterised as instances of 'wrongful' litigation due to their closeness to dispute resolution, thus potentially leading to the application of the more stringent test applied to vexatious litigation. These cases have, however, been distinguished from the situation faced in *ITT Promedia*, leading to a more interventionist approach, even though technically under the same standard of articles 101 and 102. As a result, each set of circumstances might lead to a differing approach, depending on how it is described. Indeed, there might be good reasons for distinguishing various circumstances rather than putting everything under the same label. It is in fact an argument running throughout this thesis that desirability of antitrust intervention might depend on the underlying regulatory framework applying in an individual set of circumstances and the availability of alternative solutions to the problem at hand.

II ...not matched by in-depth consideration of impact

4. Even though the Commission and the Court of Justice considered reverse payment settlements, abuse of the patent system and the question of the use of injunctions in the SEP context to be issues warranting antitrust intervention, this readiness to intervene was not necessarily matched by an in-depth analysis that would allow for the balancing of the diverging innovative interests at stake. In getting involved in patent issues, antitrust got involved in the question of balancing of incentives to innovate as promoted through exclusivity and competition. It also got entangled in questions of balancing of interests of breakthrough and follow-on innovators (as perfectly exemplified by the *Huwawei v ZTE* case). Yet its reasoning did not always prove to be satisfactorily embracing the balancing of those interests.
5. The decisions of the Commission and the Court of Justice were prone to have an impact on the functioning of the patent system, potentially acting to rebalance it and to curtail its use. Without a proper consideration of the consequences of such move, the

[1] See ch 10, para 13 ff.

decisions might have been undermining the innovative function of the patent system. Where the patent holder's actions can be justified by patent policy, this should have a bearing on the finding of anticompetitiveness. Such considerations can be easily included within antitrust analysis by incorporating competition in innovation, and not just competition on price, within the analysis.

6. Furthermore, when faced with uncertainty arising out of patent context, the Commission and the Court faced some problems in establishing a viable counterfactual, as the situation of reverse payment settlements has shown. This example shows that antitrust authorities might be constrained in their ability to viably assess certain situations. Second guessing patent assessments on the basis of scrap information might not be the best way to proceed. It is deemed to create false positive results which might be detrimental to innovation and also potentially puts antitrust findings in conflict with patent law.

7. Admittedly, demanding higher reasoning standards comes at a cost, higher accuracy is always a strain on the resources of a competition authority and might undermine the goal of administrability of the system. However, in discussing novel issues, like the ones analysed in this Part, it is imperative that the Commission understands well all the elements at play and performs the appropriate balancing before taking a short-cut to simplified solutions to make sure that no fundamental errors are committed. The situations considered were not obviously pointing in a single direction, despite what has been concluded (in particular in respect of reverse payment settlements) and thus deserved a fuller scrutiny, especially in light of the impact they might have on the innovative process.

III Innovation angle not at the forefront of the analysis

8. Considering that the analysed decisions raised questions of interaction between antitrust and patent policies, it was expected that innovation would play a decisive role in the underlying reasoning, this being a common denominator between the two spheres of law and taking into account that the decisions concerned industries that are R&D driven. The difficult part of antitrust analysis in the patent context should be valuing of different factors against themselves, not making them part of the equation. Competition in innovation and the question of the parties' incentives was however not

at the forefront of the analysis. The decisions concerning reverse payment settlements and AstraZeneca both concentrated on the question of generic entry seemingly from the perspective of short term goals and competition on price. In that sense the approach of the authorities might be reflective of a more general problem going beyond the sphere of decisions touching on patents whereby innovation and long term goals are not treated sufficiently seriously within antitrust analysis which focuses on short term goals. For example, the problems of proving an innovation-based or an efficiency based defence (as discussed in connection to reverse payment settlements) are not particular to the patent context. In this way, however, the Commission restricts the role of antitrust policy and potentially puts it in conflict with patent policy.

9. While the focus on short-term goals was not so apparent in the SEP injunctions decisions, the reasoning of those cases did not focus on the balancing of incentives between breakthrough and follow-on innovators either. Instead, the analysis was shrouded in the fundamental rights language, which worked to undermine rather than to highlight patent policy interests. In effect, in none of the cases considered in Part II the acknowledgement of the importance of patents in promoting innovation translated into an in-depth discussion of the balance to be struck between the requirements of patent policy and antitrust. Admittedly, in some instances the Commission and the Court addressed challenges based on patent policy (for example in respect of asymmetry of risk in the context of reverse payment settlements), but these arguments were swiftly dismissed, often on grounds that had nothing to do with what was at the heart of the challenge, which was the balance between antitrust and patent policy demands as seen from the innovation perspective.

10. Similarly, the Sector Inquiry Report's findings were very limited in respect of the innovation dimension, despite the fact that reduction in the level of innovativeness was one of the reasons for initiating the inquiry. The misguided focus of the sector inquiry is particularly problematic for it is a document that is likely to guide future antitrust enforcement, as already suggested by the approach to reverse payment settlements. The Sector Inquiry report might also have an inadvertent chilling effect on innovation because of the uncertainty it brought about by suggesting that certain patent practices might be suspicious from the competition perspective without openly saying so.

IV Pro-competition bias

11. In handling cases at the antitrust-patent intersection the Commission and the CJEU might have both displayed signs of a pro-competition bias. This is meant to say that they showed an undue preference for the promotion of innovation through competition rather than through exclusivity as pursued by the patent policy as a result of a one-sided perception of the problems they faced. To an extent such preference might be said to be inbuilt in the work of the Commission acting as a specialised agency entrusted with enforcement of antitrust law. It might be also inbuilt in the legal tools available to the Commission, as can be illustrated by the difficulty of proving a defence based on innovation. Pro-competition bias can be discernible in a variety of ways, but it comes down to pushing through a competition law solution to an innovation problem while understanding competition in a limited, single-dimensional way as competition on price that nearly always favours the entrant. The pro-competition bias becomes apparent through downplaying the significance of patent policy in shaping the conditions of competition or by ignoring the impact of an antitrust decision on patent policy. It can be exemplified by taking an anti-patent holder position since it is the one that personifies the barrier to competition. Such bias, however, can be difficult to measure, in particular if only looking at the outcomes of cases. Equally though, when looking at the underlying reasoning, the perception of one-sidedness in the Commission decisions can be caused by the prosecutorial role it plays. The Commission decisions need to justify a finding of an infringement, so it is not surprising that the arguments against the patent holder become more visible in the analysis. Making a credible argument for a finding of liability though should also involve dispelling arguments to the contrary, if only to show that a particular point of view was taken into account in making a decision.

12. The analysis of the decisions under consideration in this thesis has shown that the existence of a pro-competition bias might be a real risk. Both the Commission and the Court failed to seriously embrace the multifaceted nature of the competition process, which includes competition in innovation as enabled by the patent system. Both also seemed to have approached the patent system with distrust, being sceptical of the way in which it functions, while at the same time making questionable patent assessments in the process. If unsubstantiated, such assessments might lead to results detrimental to innovation and be a sign of a biased position. The formal legal analysis not grounded

in economic thinking about the parties' incentives might have also worked to hide possible pro-competition bias from sight. This was well visible in the SEP injunction cases, in which the unbalanced outcome skewed towards the would-be-licensee reflected the unbalanced reasoning of the decision that was grounded in fundamental rights analysis that downplayed one side of the equation.

13. One way of looking at the pro-competition bias is to see it as downplaying external considerations, a problem that might be known to any administrative agency, not just specific to competition authorities. A solution to that problem would be to internalise it by making it part of competition analysis. The flexibility afforded to antitrust analysis through the multifaceted nature of the competition process and the fact that protection of innovation is one of the goals of competition law makes such internalising a real possibility. The above could suggest that a pro-competition bias is a problem that is particular to administrative decision-making that might be corrected by the possibility of a revision before a court. However, the Court of Justice is also likely to display a pro-competition bias, as has been indeed suggested by the case studies discussed here. Even though it entertains a relatively wide jurisdiction, it is still a specialised court with a limited jurisdiction over intellectual property matters and seized of a competition matter.[2] As such it is prone to display biases in the same way as any specialised court. The possibility of specialised courts displaying biases in their decision making is discussed further in the next chapter in connection to the parallel position of the Unitary Patent Court (UPC).

V Industry sensitivity

14. It has been noted at the outset of this thesis that the case studies come from two contrasting industries - pharmaceutical and the ICT. This raised a question whether any difference in treatment could be warranted on the basis that innovation process is said to be operating differently in those industries, with a different emphasis being put on the importance of patents. The analysed cases, however, did not suggest that the principles established therein were limited or devised with a particular industry in mind. The Commission and the CJEU failed to fully embrace the innovation angle in respect of both sectors. The regulatory set up was considered solely as background to

[2] In contrast with the US Supreme Court.

the decisions. The sensitivity to the dynamics of the operation of particular industries in so far as this formed the legal and economic context of the analysed issues could be described as mixed. Reference to the practicalities of the functioning of the pharmaceutical industry seemed to matter more when it came to the position of the would-be-entrant. For example, in *AstraZeneca* the existence of a wrongfully granted SPC mattered when discussing deterrents on potential competition, but the potential deterrent effect on patent application that a wide scope of liability could have was not considered equally seriously.

15. As for the question whether the particular European regulatory background changed anything in the application of antitrust to a given problem, there appears to be no clear answer to it. When discussing reverse payment settlements, a comparison with the US practice was made. Although the US regulatory set up of the pharmaceutical industry under the Hatch-Waxman Act could be said to change the incentives of the parties, lack of a similar system in Europe did not radically change the assessment of those agreements, though the US and the EU approaches are not identical. If anything the implicit trade-off made as part of the sector specific regulation in the US could strengthen the case for antitrust intervention. However, the EU response so far proved to be even stronger. Similarly, the existence of well-developed alternative solutions did not work to differentiate the US approach to injunctions in the SEP context. The US approach could suggest an explanation for antitrust involvement that is not grounded in the perception of failure of the patent system or perhaps that the US alignment with EU practice was not justified in that instance. Yet, the US approach should not necessarily be treated as an optimal benchmark against which to measure the EU response, it only served to identify the key characteristics of the EU approach.[3]

VI Alternative solutions? Antitrust as a repair-it all

16. Speaking of alternative solutions, antitrust reaction in each case analysed in this Part could be seen as provoked by the deficiencies or failures of the patent system itself, be it in handling injunctions, not providing adequate remedies to the abuse of the patent system, or by introducing undue uncertainty through patents of questionable quality into the system that relies on litigation. Reverse payments settlements, the situation

3 See further section VII below.

faced in *AstraZeneca*, and the issue of SEP injunctions could be said to be representing three different types of perceived patent system failures. In the first instance, anticompetitive abuse stems almost directly from the design of the patent system which is based on probabilistic rights, the second concerns lack of sufficient mechanisms inbuilt in the patent system for countering abuse, and the third, a situation in which sufficient legal mechanisms might already exist, but are not put into appropriate use.

17. Competition law policy of intervening in such instances could be said to be putting antitrust in a position of a "repair-it-all" mechanism. In this way it is meant to work as a second filter in circumstances where patent law or other regulatory provisions that could potentially come in use in the patent context do not provide a solution. Although in this way antitrust could be said to be exercising its pro-innovative function by supplementing the patent system, the *AstraZeneca* case has shown that the result might not be that obvious - heavy-handed solutions might have the opposite effect.

18. In general, It is not clear whether antitrust is always the best solution to patent problems. For one thing, there are disadvantages inherent in antitrust case-law intervention connected to the uncertainty it inevitably brings about (arguably, this uncertainty could be limited in some instances by paying more attention to the scope of liability, as can be illustrated by *AstraZeneca* and *Lundbeck* judgments). Moreover, approaching those issues through patent law might seem more natural, this being the field of law as a matter of which the original balancing of interests was made. In the abstract it would seem that it should be easier to decide as a matter of patent policy whether a particular conduct was meant to come within the scope of those deemed acceptable by that policy. However, one also needs to look at the regulatory reality in which achieving that might be difficult or impossible. Also, in the EU regulatory context patent authorities might lack a common voice,[4] as might have been the case for example with the issue of injunctions as discussed in connection to SEPs.

19. Still, it is important to see the patent system as whole, consisting both of the patent granting stage (affected in the *AstraZeneca* case) and the system of patent litigation (as touched upon in *Lundbeck*/*Servier* and in respect of SEP injunctions). While litigation concerns mostly post-grant issues, it might also occur through the EPO's opposition proceedings. Moreover, the patent litigation system is not self-contained - it relies on a

[4] See ch 9 for the discussion of the fragmentation of the patent system.

variety of general law provisions for its functioning, and this extends not just to procedural issues, but also substantive law provisions (such as rules of equity or fraud). The application of those rules by the forthcoming Unitary Patent Court (UPC) might become a challenge. It is yet to be seen how it will handle it.

VII Comparison with the US

20. In analysing the case studies, the European approach to issues at the antitrust-patent intersection has been compared to that taken in the US. This helped identifying characteristic features and possible deficiencies in the European approach. The relative openness of discussion visible in the US courts, characteristic of the common law approach, was helpful in fleshing out the key arguments at stake. While some issues featured earlier in the US jurisprudence, the problems that might arise out of taking a particular approach were already known to the European decision-makers. This is particularly so in respect of the treatment of reverse payment settlements. The Commission and the General Court, however, were not prepared to draw on the lessons to be learnt from the cases post-dating *Actavis*. To the contrary, the Court relied on *Actavis* with approval specifically on the point that has been shown to be lacking. In fact, when it comes to the scope of liability, in *AstraZeneca* the Court refused to entertain arguments drawing on the US approach as developed in the *Walker Process* case to support an argument to restrict the scope of liability to fraud or wilful misrepresentation. The general attitude of the European competition authorities appears to be to reject such arguments on formal grounds that the EU is not in any way bound by the US jurisprudence. Even though this is without doubts correct, it avoids addressing issues that are at the heart of such arguments. Engaging with those arguments could be beneficial for clarifying why the European take on those issues goes one way or the other.

VIII Innovation in antitrust vs innovation in merger analysis

21. As explained in the introductory chapter, the analysis performed in this Part centres around decisions under either article 101 or 102, rather than merger cases, since the focus is on the treatment of novel issues. Merger analysis might however remain relevant for the assessment of the approach taken by the Commission and the CJEU to

antitrust cases as a contribution to the understanding of harm to competition.[5] Indeed, merger analysis is said to have experienced a convergence with antitrust following the changes introduced in 2004 by the reform of merger control. The new SIEC test ('significant impediment of effective competition') is meant to be substantively similar to the concept of 'restriction of competition' under article 101.[6] Some of the concepts used as part of merger analysis, such as those potential competitors, are also meant to operate in parallel.

22. Thus, it is interesting to see that merger analysis in recent years has shown a revived interest in innovation. [7] While the changing enforcement practice might be equally a result of the growth in importance of the high-tech markets as much as of the changing approach of the Commission, it becomes significant also from the antitrust perspective. If there is anything to be learnt from merger practice it is the focus on the incentives of the parties in analysing the counterfactuals. The focus of merger analysis is on how a given transaction might affect future incentives of the parties and their competitors, including the incentives to innovate, be it through enlarged patent portfolio or otherwise. In the antitrust context such analysis would need to extend to analysing the legal position of patent holders and would-be-entrants going beyond the position of the individual parties to the case, considering the wide impact an individual antitrust decision might have (to that effect, the discussion of the impact of *AstraZeneca* might be of use). It is interesting to see though that in merger analysis

5 Carles Esteva Mosso, "The Contribution of Merger Control to the Definition of Harm to Competition", speech of 01 February 2016 given at GCLC Conference.

6 ibid, p 8; noting, however, that the 'by object' analysis under art 101 follows different standards.

7 Recent Pharmaceutical merger decisions are said to be a good example of the increased interest of the Commission in innovation: Carles Esteva Mosso, Head of Merger Policy at DG COMP, on 12 January 2016 at an event organised by Brussels ULB University, "Les Mardis du Droit de la Concurrence"as cited by Frederic Jenny, "Merger trends in innovation markets on the two sides of the Atlantic", available at https://antitrustlair.files.wordpress.com/2016/11/jenny-merger-trends-in-innovation-markets.pdf (accessed 1 March 2017), p 75. Cf Justus Haucap and Joel Stiebale, "Research: Innovation Suffers When Drug Companies Merge" (3 August 2016) Harvard Business Review (empirical research suggesting that mergers and acquisitions in the pharmaceutical sector reduce innovation and R&D of both merging entities and of competitors). Some recent merger cases in which innovation played a role include: M.7217 *Facebook/WhatsApp*, M.7275 *Novartis/GSK Oncology Business*, M.7278 *GE/Alstom*, M.7326 *Medtronic/Covidien*, M.7477 *Halliburton Co./Baker Hughes*, M.7559 *Pfizer/Hospira*, M.7688 *Intel/Altera*.

reduced competitive pressure is deemed to have a negative effect on innovation.[8] If directly translated into antitrust context this could be taken to suggest a benefit of a strong pro-competitive stance directed against patent exclusivity. In merger context, however, the competition law is not put in a position of potential conflict with patent policy. Eventual restriction of the right to dispose of a patent right might be attributed to the special position of the dominant players who are parties to the merger transaction akin to 'special responsibility' seen in the context of article 102. The effects are limited to a particular transaction and do not possibly affect patent policy more widely.

23. It is interesting to see though that *ex post* evaluation of mergers seems to suggest that the Commission might be too lenient in its review looking at it from the innovation perspective, since studies into the pharmaceutical sector suggest that R&D and innovation levels tend to fall following merger transactions both in respect of the merged entity and its competitors.[9] Putting these results against the findings of the sector inquiry report could imply an alternative explanation, grounded in the market structure, for the fall of innovative activity in the pharmaceutical sector that need not have anything to do with patent strategies. While these are not mutually exclusive, it still puts the findings of the sector inquiry in a different light.

24. Another element of merger analysis that might be of interest in the current context might be industry specificity of the analysis in so far as it relates to the innovation process. In recent merger decisions the Commission considered the length of innovation cycles as a relevant aspect of measuring market power.[10] While the Commission tries to embrace the dynamic nature of competition and the changing competitive conditions in light of the innovative processes that take place in the market (or that might indeed change the nature of the market), merger market analysis also faces challenges in terms of the standard of proof akin to antitrust enforcement. This further exposes the limits of the analytical tools available to competition authorities in analysing the innovation context.

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8 Case T-175/12 *Deutsche Börse AG v Commission* ECLI:EU:T:2015:148; cf Case no M.5984 *Intel/McAfee* in which harm to innovation was considered independently from foreclosure effects.

9 Haucap and Stiebale (n 7).

10 See e.g. M.7217 *Facebook/WhatsApp*, para 99; M.6281 *Microsoft/Skype*, para 83.

IX Conclusions

25. This Part served to identify the key features and potential problems with antitrust involvement in patent matters looking at the problem from the innovation perspective. It has shown that an approach grounded in separate treatment that confines antitrust to a more limited role is prone to lead to a risk of a pro-competition bias thus potentially undermining the patent system and acting to the detriment of innovation. It also might have the effect of putting antitrust and patent policies in conflict even though they are said to have the same goals. By these standards, a successful antitrust involvement in patent matters would need to become a platform for the balancing of often diverging interests at stake.

26. Taking into account the inherent limitations of antitrust scrutiny and the potential for a pro-competition bias, the question of interaction between antitrust and patent law becomes a matter relevant from the innovation perspective. The balance struck between innovation through competition or through patent exclusivity might actually depend on which regulatory bodies are seized of the issue. As it will become apparent from the next chapter, patent courts might be just as likely to display a pro-patent bias pulling in the opposite direction than a pro-competition bias displayed by the antitrust authorities. Thus, in deciding to intervene, it might be also worth considering whether a given forum is the best forum for dealing with a given problem.

Part III

Chapter 9

The intricacies of the European institutional legal framework

I Introduction

1. Although the enforcement of EU competition law has been decentralised through the introduction of Regulation 1/2003,[1] which created a framework that allowed national competition authorities (NCAs) and national courts to directly apply the provisions of articles 101 and 102,[2] the Commission retained its position as a "guardian of the Treaty" which has "the ultimate but not the sole responsibility for developing policy and safeguarding consistency when it comes to the application of [EU] competition law".[3] Its position as a central policy maker is realised not only through its taking of a leading role within the European Competition Network (ECN),[4] but also through the formal powers conferred upon it by the Modernisation Regulation, which include the ability to make written observations in cases before the national courts[5] and to relieve the NCAs of their competence to apply articles 101 or 102 by initiating proceedings of its own.[6] It is because of this leading role of the European Commission as an antitrust policy maker that Part II looked into antitrust enforcement at the European level, rather than at national decisions.
2. The situation is different when it comes to creation of patent policy. This chapter explores the fragmented nature of the European patent system in order to inform the discussion about the interaction between the bodies responsible for antitrust and

1 [2003] OJ L1/1.

2 Previously, under Regulation 17 ([195-62] OJ Spec. Ed. 87), application of article 101(3) to individual agreements was within the exclusive competence of the Commission, which under art 9(1) had the "sole power" to declare article 101(1) inapplicable. Thus, all agreements would have to be notified to the Commission in order to obtain an individual exemption.

3 Commission Notice on cooperation within the network of competition authorities [2004] OJ C 101/43, para 43. The Member States retain a residual role in creating national competition law and are not precluded from applying stricter rules to unilateral conduct of undertakings, or to agreements, decisions of associations or concerted practices where these do not affect trade between Member States (art 3(2) Reg 1/2003).

4 Still, decentralisation brought with it a challenge of maintaining an alignment of purpose: Imelda Maher, "Functional and normative delegation to non-majoritarian institutions: The case of the European Competition Network" (2009) 7(4) Comparative European Politics 414.

5 Art 15(3).

6 Art 11(6); the Cooperation Notice (n 3) indicates, however, that the Commission will make use of art 11(6) after the case allocation phase only in specified circumstances, which include situations where a national authority envisages "a decision which is obviously in conflict with consolidated case law" or where there is "a need to adopt a Commission decision to develop Community competition policy...", para 54.

patents policy creation, and also with a view to highlighting the significance of the forthcoming Unitary Patent Court (UPC) as a policy maker (section II). The new European patent court, as envisaged by the Unitary Patent Court Agreement (UPCA), is set to be a highly specialised institution. It is thus inherently exposed to a risk of a pro-patent bias operating in the opposite direction than the pro-competition bias explored in Part II. The essence of the pro-patent bias is the preference for a pro-patent holder solution grounded in patent expansionism in situations in which a pro-innovation policy requires a balancing of interests. The signs of a potential for a pro-patent bias on the part of the patent courts or patent authorities were already hinted at in the previous Part, in particular in connection to SEP injunctions. The semi-automatic granting of injunctions in the SEP context without regard to competition arguments or arguments grounded in follow-on innovation could be seen as an illustration of that risk just as much as the extreme pro-patent holder position taken by the German courts under the *Orange Book* standard.[7] The purpose of this chapter is thus to show that the problem of bias in the decision reasoning does not concern only the application of antitrust to patent matters, but can also operate in the opposite direction in the context of patent litigation. This is significant for it serves to show that each field of law might be pulling in the opposite direction at the expanse of innovation. Consequently, an attempt at achieving results balanced from the innovation perspective might require targeting both kinds of biases.[8]

3. While the institutional set-up of patent litigation in Europe is about to undergo major redevelopment, the risk of bias in the patent context is explored though an analysis of institutional design rather than through case-law analysis. As the UPC is not yet functioning, the discussion surrounding the US experience with its own specialised patent appeal court, the Federal Circuit Court of Appeal, is used here to identify factors that might contribute to the risk of bias (section III). This in turn will allow for determining the structural safeguards that might be used to limit that risk in hope of securing more balanced results (section IV). The nature of the interaction of the UPC with the CJEU (section V) and the EPO (section VI) might also be significant in this context.

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7 See ch 6, paras 20-21 and 50-52 for details.

8 See further ch 10.

II The fragmented nature of the patent system in Europe

4. Until recently, the EU involvement in patent matters was very limited. Indeed, not so long ago the CJEU considered that there is no Community patent legislation.[9] Unlike other intellectual property rights, patent law remains un-harmonised at the EU level, despite calls for harmonisation spreading over decades.[10] Mostly because of disagreements about the shape such harmonisation should take, the EU involvement is thus far limited to several distinct matters, such as patentability of biotechnological inventions,[11] supplementary protection certificates,[12] and separate form of protection afforded to plant varieties.[13] The most notable piece of legislation that has an effect on patents granted in the Member States is the Enforcement Directive setting standards for remedies and penalties available in the event of infringement. Nonetheless, protection of intellectual property, and so also patents, is ensured within the EU legal order through article 17 of the Charter, as mentioned in connection to *Huawei v ZTE*.

5. Yet, some level of harmonisation is achieved at the European level, if not at the EU level, through the European Patent Convention (the EPC), an international agreement under which the European Patent Office was established. The EPC, as revised in 2000 *inter alia* to bring it in line with the requirements of the TRIPS agreement, provides substantial provisions relating to patentability and validity and establishes an autonomous mode for filing for a European patent through the EPO which performs application examination. Although it is possible to apply with a single application, the grant is then transformed into a bundle of national patent rights governed separately by each of the signatory States (there are currently 38 parties to the Convention, including all the EU Member States). The question of patent infringement is thus within the exclusive competence of national courts or tribunals. Only pre-grant issues, such as

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9 Case C-431/*05 Merck Genericos - Produtos Farmaceuticos Ld v Merckand Co INc Merck Sharp and Dohme Ld* [2007] ECR I-07001, para 40 ("As Community law now stands, there is none").

10 Already in the 1960s an EEC patent was considered: Catherine Seville, *EU Intellectual Property Law and Policy* (EE 2009), p 91.

11 Directive 98/44/EC of 6 July 1998 on the legal protection of biotechnological inventions [1998] OJ L 213/13.

12 As discussed in Ch 4 in relation to *AstraZeneca*; Council Regulation (EEC) No 1768/92 concerning the creation of a supplementary protection certificate for medicinal products (codified as Regulation (EC) no 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products).

13 Council Regulation 2100/94 of 27 July 1994 on Community plant variety rights [1994] OJ L 227/1.

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opposition proceedings, are brought before the Boards of Appeal established next to the EPO.

6. The Member States, however, are not at liberty to develop patent protection freely, not only because they are all part of the EPO, but also because they are all WTO members (as is the EU itself) and so signatories to TRIPS. This international agreement, operating as an annex to the WTO agreement, sets minimum standards regarding *inter alia* patent protection, including provisions on remedies, dispute resolution, and enforcement procedures. Furthermore, some Member States are also contracting states to the Patent Law Treaty which harmonises formal procedures for patent applications.[14] The EPO has signed, but not ratified that agreement as of yet. Just like at the EU level, however, attempts at harmonising substantive patent law at the wider international level have been marked by difficulties. WIPO's Standing Committee on the Law of Patents has been working on harmonisation of substantive patent law, however it arrived at a stalemate position, with the major line of disagreement arising between developed and developing countries.[15] Interestingly, the developing countries were, among other things, pushing for inclusion of provisions on anti-competitive practices in the Treaty.[16] These issues, however, proved to be too controversial and consequently a group of developed states, including the EU Member States, the European Commission and the EPO, broke away in an attempt to break the deadlock and agree on a harmonisation within a smaller circle. More than ten years later, the achievements of the Group B+, as it is called, can be summarised as "work in progress".[17]

7. It is against this complicated background of overlapping international obligations, that the European Commission pushed for a unitary patent. The proposal for a unitary patent gained momentum following a failure of the European Patent Litigation Agreement aimed at creating a common judicial system for the EPO States.[18] The process started with a Commission consultation initiated by DG for Internal Market,

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14 Croatia, Denmark, Estonia, Finland, France, Ireland, Latvia, Lithuania, the Netherlands, Romania, Slovenia, Sweden, and the United Kingdom.

15 Seville (n 10), p 89-90.

16 Seville (n 10), p 89.

17 https://www.epo.org/news-issues/issues/harmonisation/group-b-plus.html (accessed 27 Nov 2016).

18 It was intended as an optional Protocol to the EPC. The Agreement was dropped following a negative interim opinion of the Commission's legal service which considered the agreement to be contrary to article 292 of the EC Treaty, http://www.ipeg.com/_UPLOAD%20BLOG/Interim%20Legal%20Opinions%20Legal%20Service%20EP%20Feb%201%202007.pdf (accessed 27 Nov 2016). See Trevor Cook, *Intellectual Property Law* (OUP 2010), 533 ff for a summary of the attempt to create EPLA.

Industry, Entrepreneurship and SMEs in 2006.[19] Eventually, due to a disagreement concerning translation arrangements, it was decided that an agreement on the unitary patent protection will be concluded using enhanced cooperation procedure, with Italy and Spain unwilling to join.[20] Eventually, 25 out of 28 Member States decided to participate (with Poland, Spain and Croatia declining to adhere). The enhanced cooperation route to creating a unified patent has been unsuccessfully challenged before the Court of Justice,[21] with the result being that it is set to create an even more fragmented patent system in Europe.

8. The EU Unitary Patent package consists of two pieces, only the first of which is already in force.[22] The Unitary Patent has been created by two Regulations, the first one containing substantive provisions[23] and the second one translation arrangements.[24] In addition, the Unitary Patent Protection Regulation foresees creation of a Unitary Patent Court (UPC), as an essential element to the functioning of the unitary patent system.[25] This resolve to provide common system of judicial protection has been realised through an international agreement, which still awaits ratification .[26] The system thus created provides for an alternative to a national bundle of patents. Patent holders applying for a European patent through the EPO will henceforth have an opportunity for their patent to have a unitary effect in the participating Member States.[27] A patent with a unitary effect will enjoy uniform protection in all the Member States and will become subject to the exclusive jurisdiction of the UPC. This will

19 European Commission Press Release IP/06/38 of 16 January 2006, "Commission asks industry and other stakeholders for their views on future patent policy".

20 In accordance with art 20 TEU and arts 326 and 329 TFEU, and pursuant to art 118 TFEU as the legal basis. See Council Decision of 10 March 2011 authorising enhanced cooperation in the area of the creation of unitary patent protection 2011/167/EU (2011) OJ L76/53.

21 Joined cases C-274/11 and 295/11 *Kingdom of Spain, Italian Republic v Council of the European Union*, ECLI:EU:C:2013:240, ECLI:EU:C:2012:782; Case C-146/13 *Kingdom of Spain v European Parliament and Council of the European Union* ECLI:EU:C:2015:298.

22 The Regulations entered into force on 20th January 2013. However, they will only apply when the Unitary Patent Court Agreement enters into force (art 18(2)), which is when at least 13 Member States ratify the Agreement, including three with the greatest number of patent applications (currently France, Germany and the United Kingdom).

23 Regulation (EU) No 1257/2012 of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection (Unitary Patent Protection Regulation).

24 Council Regulation (EU) No 1260/2012 of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection with regard to the applicable translation arrangements (Translation Arrangements Regulation).

25 Recital 25 of the Regulation (n 23), ("Establishing a Unified Patent Court to hear cases concerning the European patent with unitary effect is essential in order to ensure the proper functioning of that patent, consistency of case-law and hence legal certainty").

26 Council Document No 16351/12 of 11 January 2013.

27 Art 3 of the Unitary Patent Protection Regulation (n 23), in respect of European patents granted with the same set of claims.

prevent the need for multiple litigation, but it also means that revocation will have a more wide-encompassing effect. It is hoped that the unitary patent system will reduce the cost of patenting in Europe (through *inter alia* simplified translation arrangements) and create more legal certainty. Optimists predict that the introduction of this new system will lead to national patenting practices disappearing in time. [28] The success, or indeed coming into effect,[29] of the Unitary Patent system is, however, by no means a done deal. The Agreement has not as of yet been ratified, and the story of patent harmonisation of patent protection in Europe has already witnessed signed agreements that have never come to fruition.[30] Even if the UPC comes into existence and manages to establish its position as a reliable patent court, the patent holders might still have strategic reasons to prefer national patenting. Also, smaller entities, operating only locally, might still turn to the national patenting systems. In effect, it is to be expected that the patent system will at best be even more multi-layered and complicated than before.

9. Significantly, the unitary patent system established through the Regulations contains hardly any substantive patent law provisions. Instead, reliance is put on the EPC and the EPO who will be left in charge of administering the system.[31] The question of the scope of protection afforded by the unitary patent is thus left to a body external to the EU legal system and only subject to review by the UPC.

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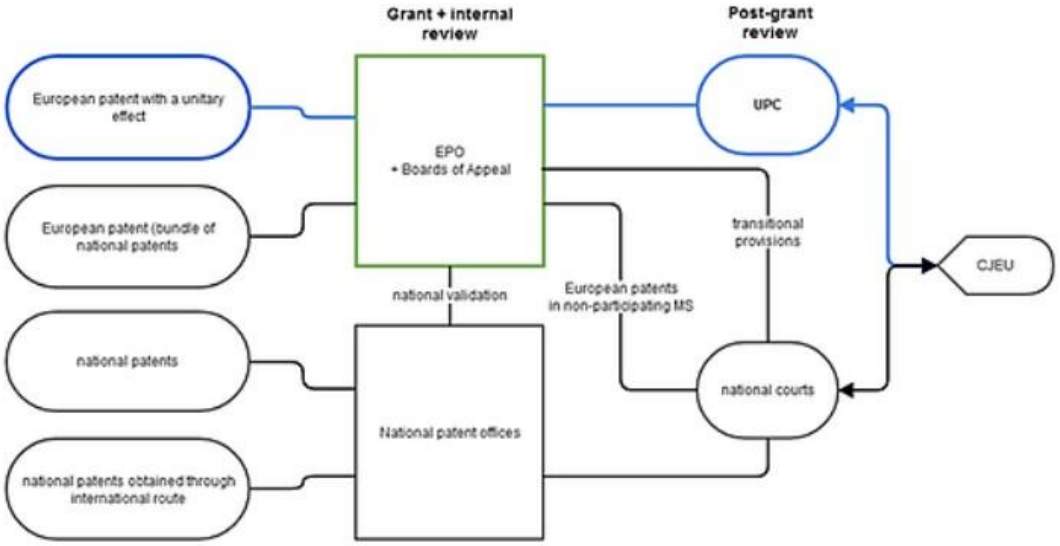
28 Clement Salung Petersen, Thomas Riis, Jens Schovsbo, "The Unified Patent Court (UPC) in Action: How Will the Design of the UPC Affect Patent Law?", in Rosa Maria Ballardini, Marcus Norrgard, and Niklas Bruun (eds), *Transitions in European Patent Law: Influences of the Unitary Patent Package* (Wolters Kluwer 2015), p 37 ("Inevitably, the national practices will dwindle and in time disappear").

29 See Thomas Jaeger, "Shielding the Unitary Patent from the ECJ: A Rash and Futile Exercise" (2013) 44 IIC 389, listing some of challenges to the legality of the system that might be lying ahead.

30 The Community Patent Convention of 1975 was signed but never ratified by a sufficient number of Member States.

31 Art 9 of the Unified Patent Protection Regulation (n 23).



10. As the diagram above shows, the system will be more multilayered than before. Even if a patent holder decides not to request unitary patent protection, if they apply for their patents through a European route, that is through the EPO, their patents will be still subject to the exclusive competence of the UPC, but only in respect of the patents granted in the participating States. Yet, the Agreement envisages a transitional period, during which European patents without a unitary effect will still be considered by national courts. Furthermore, If the patent holders apply also for protection in one or more of the non-participating States, any post-grant proceedings will have to be considered by the national courts of those States. The review of the work of the EPO and its Boards of Appeal by the UPC will equally only have effect in respect of patents in so far as they have effect in the participating Member States. It will be thus possible to partially reverse the outcome of opposition proceedings before the EPO that had until now a unitary effect, destroying some of the unity achieved through the common application and examination system.

11. Doubts about the popularity of the unitary patent aside, it seems that within this new arrangement the UPC is likely to become a key patent policy creating body. It is in the very nature of patent law that a lot is left to the courts. It is after all the courts that apply the very abstract concepts of patent law to real life situations, giving them meaning and thus shaping patent policy. In the new system the UPC will have a final say over a great portion of European patents previously conclusively managed by the EPO and the national courts. It will be given a role in managing the interplay of

national, international, and European patent law.[32] At the same time, the review of the UPC's work by the CJEU is set to be limited. The review of the operation of the Court by the Administrative Committee set up at the UPC is likely to be limited to procedural matters and in any case any significant changes that would be called for as a result of such review would probably require legislative changes.[33] Seeing how legislative amendments of substantive patent policy are difficult to achieve because of the disagreements between States and the complicated net of international obligations already in place, the UPC will most probably be left with a considerable freehand to develop its own patent policy.

12. Will this new Court manage to bring uniformity to the European patent system or make the system even more fragmented? There seems to be no obvious answer to that question. At the institutional level at least, it seems to be adding to the fragmented nature of the patent system. The ideal of the one-stop shop has not been realised by the use of the enhanced cooperation procedure and multiple litigation cannot altogether be eliminated by this multi-layered system. As for the substantive level, there is a question of how much discrepancy there actually is today. The existence of 28 parallel patent systems should not lead to an exaggeration of the differences as they appear in practice. The EPO's Boards of Appeal have taken on a leading role in establishing standards of patentability, becoming the "commodore of a convoy of ships" when it comes to interpretation of the EPC.[34] The Member State patent offices and courts try to follow the lead of the EPO in parallel cases[35] and national courts also seek consistency between each other.[36] As it was tellingly put by Justice Jacobs in the *Scotts Potato Machinery* case before the English Court of Appeal:

> Broadly we think the principle in our courts - and indeed in the Courts of other Member States - should be to try to follow the reasoning of an important decision in another country. Only if the court of one state is convinced that the reasoning of a court in another Member State is erroneous should it depart from a point that has been authoritatively

32 See art 24 of the UPCA specifying the sources of law on which the UPC is to rely.

33 As foreseen by art 87 UPCA.

34 *Actavis UK Ltd v Merck & Co Inc* [2008] EWCA Civ 444, [2008] RPC 26, paras 47-48.

35 *Human Genome Sciences Inc v Eli Lilly and Co* [2011] UKSC 51, [2012] RPC 6.

36 *Conor Medysystems Inc v Angiotech Pharmaceuticals Inc* [2008] UKHL 49, [2008] RPC 28. According to the Pharmaceutical Sector Inquiry Report, conflicting results were achieved in 11 per cent of the final judgments under scrutiny (para 664).

> decided there. Increasingly that has become the practice in a number of countries, particularly in the important patent countries of France, Germany, Holland and England and Wales. Nowadays we refer to each other's decisions with a frequency which would have been hardly imaginable even twenty years ago. And we do try to be consistent where possible.
>
> The Judges of the patent courts of the various countries of Europe have thereby been able to create some degree of uniformity even though the European Commission and the politicians continue to struggle on the long, long road which one day will give Europe a common patent court.[37]

The success of the UPC might thus depend on its ability to take over the leading role of policy making from the EPO and gaining trust of the national courts. This might turn on its ability to deliver balanced solutions that favour innovation policy.

III A highly specialised UPC and the potential for a pro-patent bias

13. The UPC is designed to be a specialized court, i.e. a court whose jurisdiction is defined and limited by the subject-matter of the cases it hears, rather than by geographic boundaries.[38] It will also be a "centralised" court in that it will have an exclusive jurisdiction to hear *all* cases concerning unitary European patents and (following the transitional period) European patents, as well as corresponding supplementary protection certificates.[39]

14. Specialized courts may offer many advantages. These include efficiency, obtained through a division of labour and the resulting familiarity with the subject matter, which in turn translates to quicker adjudication. The relative speediness of patent adjudication might be considered an advantage also from a competition perspective, since markets might open-up quicker in the event of the decision going against the patent holder. Furthermore, familiarity with the subject-matter caused by

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37 *Grimme Maschinenfabrik GmbH & Co KG and Derek Scott (t/aScotts Potato Machinery)* [2010] EWCA Civ 1110, at 80-81.

38 As opposed to a "generalist" court. See Edward K Cheng, "The Myth of the Generalist Judge" (2008) 61(3) Stanford Law Review 519, 526 for a discussion of the controversy surrounding the term "specialised court" and the degree of specialisation required to consider a court a "specialised court".

39 Art 32 UPCA, listing the types of actions over which the UPC is to have an exclusive competence. The remainder is left within the competence of national courts (Art 32(2)).

specialisation leads also to development of a expertise by the judges, which should lead to higher quality of judgments. Specialist expertise might be especially important in areas of law which are considered particularly complex,[40] making patent law a prime candidate for specialisation. Indeed, the prevalent view puts doubt on the ability of generalist judges to understand patents.[41] If indeed specialist judges can offer a superior understanding of the patent issues put before them, then higher quality of judgments resulting from specialisation might mean a lesser cost of the patent system, and so a benefit to competition and innovation.

15. Yet, at the same time, there are significant risks involved in court specialisation. In particular, a specialised patent court, such as the UPC, is at risk of displaying a pro-patent bias. This risk might be caused by many factors. Firstly, a court entrusted with the specific task of regulating patent law might develop a tunnel vision[42] resulting from lack of exposure to other legal problems and interests that would put the practices that are under scrutiny by that court in their proper economic and social context. In this way, the court might misconceive the importance of patents and of their role of rewarding inventors. Moreover, the judges of the UPC are at risk of embracing the rules they are supposed to enforce. Excessive identification with the statutory scheme[43] and the mission of the court might lead to an overly pro-patent friendly attitude. A risk of disproportionate identification with the statutory scheme might be strengthened by the goal with which this court was set-up, which could be interpreted as strengthening patent protection. The goal of creating coherence and uniformity might not only prevent forum shopping, but also predispose the court to favouring pro-patent solutions, since fragmentation was previously viewed as weakening the patent system.[44] Furthermore, even though balancing of interests is inbuilt into the patent system, specialisation might lead to a "less searching scrutiny of the arguments",[45] resulting from routine treatment of the cases. The Court might, thus,

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40 Ellen R Jordan, "Specialized Courts: A Choice?" (1981) 76 Northwestern University Law Review 745, 747.

41 Petersen et al (n 28).

42 Rochelle Dreyfuss, "The Federal Circuit: A Continuing Experiment Specialization" (2004) 54(3) Case Western Reserve Law Review 769, 770.

43 Petersen et al (n 28), p 45.

44 Similarly in the US, fragmentation of patent litigation and the resulting lack of uniformity (before the establishment of CAFC) were seen as a threat to the US position in the technology industry, see Paul R Gugliuzza, "Rethinking Federal Circuit Jurisdiction" (2011-2012) 100 Georgetown Law Journal 1437, 1454 discussing Hruska Commission Report prepared as part of the Domestic Policy Review that led to creation of the Federal Circuit Court of Appeal.

45 Jordan (n 40), 748.

be predisposed to ignore arguments "relating to interests and values not by design represented in the UPC."[46]

16. The expectation that the new specialised court would be patent-friendly could also explain a business push for a centralised patent court.[47] Indeed, according to Baum interest groups are the most powerful driver of specialisation.[48] In fact, the success of the 1970s proposal for the creation of the US Court of Appeal of the Federal Circuit (CAFC) specialising in patent law is partially attributed to corporate support it gained, since that was what distinguished it from previous proposals.[49] The corporate support for a unified patent court in Europe could also be explained, however, by the increase of patent value resulting from avoiding the need for multiple litigation. This alternative explanation makes it difficult to assess whether there is indeed a business expectation that the UPC will be patent friendly.

17. Still, business expectations might drive the UPC to become business friendly, since its popularity might depend on it. In the event businesses do not put trust in the Court, they might elect to apply for patents via the national route instead. The UPC might thus be tempted to establish a reputation of a patent-friendly court to secure its position, especially in the early days. This tendency, however, might be countered by the existence of repeated players, such as vertically integrated firms or firms operating in network industries where a single invention is covered by multiple patents (like Huawei and ZTE in respect of their telecoms patents), whose interests vary from case to case and who might consequently not necessarily push for overly pro-patent solutions. Moreover, a willingness to impress might work either way if a review of the functioning of the court is foreseen.[50] Such review would need to go beyond simply measuring the percentage of cases reaching the UPC as opposed to other courts and potentially also attract antitrust interest to be an effective restraint on the Court's potential tendency to be overly patent holder friendly.

18. While the UPC is not yet functioning, the US experience with a specialised patent court might be insightful in terms of identifying the risks involved, and in particular the risk of patent bias. In that context, it should be noted that any problems

46 Clement Salung Petersen, Thomas Riis, Jens Schovsbo, "The Unified Patent Court (UPC) in Action: How Will the Design of the UPC Affect Patent Law?" (June 16, 2014), available at SSRN: https://ssrn.com/abstract=2450945 or http://dx.doi.org/10.2139/ssrn.2450945, p 10.

47 As evidenced by the Pharmaceutical Sector Inquiry Report discussed in Ch 5.

48 Lawrence Baum, *Specializing the Courts* (The University of Chicago Press 2011), 207-209 as cited in Gugliuzza (n 44), p 1457.

49 Gugliuzza (n 44), 1456.

50 Indeed, the UPCA foresees a review of the functioning of the Court: art 87 UPCA.

experienced by the Court of Appeal of the Federal Circuit (CAFC) in that area might be more significant when it comes to the UPC. This is because the UPC is set to become a much more specialised court than CAFC,[51] which is only a "semi-specialised" court.[52] In fact, other issues have been added to CAFC's docket specifically in recognition of the risk of isolationism. In this way, the majority of the cases heard by CAFC concern non-patent matters, even if it is perceived predominantly as a patent court.[53] Still, CAFC's jurisdiction is not very diverse and pertains to some specific and distinct issues, such as veterans' benefits. Consequently, the non-patent issues subject to CAFC's jurisdiction might not have a "generalising" influence,[54] which means that it might suffer from the same problems of lack of exposure as the UPC.[55]

19. The creation of the Court of Appeal of the Federal Circuit was preceded by a long debate about the benefits and risks connected to specialisation. One of the early strong voices against specialisation was that of judge Rifkind saying that "judicial process requires a different kind of expertisse - the unique capacity to see things in their context."[56] While this statement is one of general validity and could be applied to any specialised court, it needs to be read against a background of a strong tradition of generalist courts in the US.[57] Yet, even if the relative inexperience[58] with specialist courts in the US would suggest that this critique should be read with caution, some of the criticism of the Court has not abated even after years of functioning and to an extent might be taken as confirming the sentiment expressed by judge Rifkind. It should be noted, however, that a criticism of the way CAFC is functioning should not necessarily be taken as an argument against specialised patent litigation, but merely as pointing to the need to guard against the risks involved. Indeed, there are some who

51 So much so that it has been called a "much more specialised patent judiciary than ever seen before in any legal system", Petersen et al (n 28), 44.

52 Richard A Posner, *The Federal Courts: Challenge and Reform* (Harvard University Press 1996), p 245.

53 Gugliuzza (n 44), p 1461.

54 Gugliuzza (n 44), 1465.

55 For that reason Gugliuzza (n 44) proposes to expand the Court's jurisdiction to add more commercial matters.

56 Simon Rifkind, "A Special Court for Patent Litigation? The Danger of a Specialised Judiciary" (June 1951) 37 A.B.A. Journal 425, 425.

57 Lawrence Baum, "Probing the Effect of Judicial Specialisation" (2009) 58 Duke Law Journal 1667 ("Americans typically think of judges as generalists"); Gugliuzza (n 44), p 1451.

58 CAFC is by no means the first US specialised court. The earliest court specialized by subject-matter in the US was created as far back as in 1855 (the Court of Claims) - Rochelle Dreyfuss, "Specialized Adjudication" (1990) 1 BYU Law Review 377; other subject-matter jurisdiction courts predating CAFC include The Court of Customs Appeals, the Commerce Court, the Emergency Court of Appeals, the Temporary Emergency Court of Appeals, the Foreign Intelligence Surveillance Courts and the Court of International Trade.

view the court as a great success,[59] even if other commentators point out that there is significant scope for improvement. [60]

20. Significantly though, one of the main points of criticism is that it is not sufficiently responsive to national competition policy[61] or to innovation policy.[62] This problem could be caused by the isolationism of CAFC resulting directly from specialisation or be a problem of the Court's own making. The CAFC is also widely perceived as a pro-patent holder court.[63] Other points of criticism that indirectly relate also to innovation pertain to inter alia the standard of patentability.[64]

21. Available scholarship, however, provides us only with a fragmentary understanding of the extent to which the effects of specialisation, be it positive or negative, actually occur.[65] As with any assessment of the court's performance,[66] it is difficult to measure empirically whether the court is actually biased or favours patent expansionism by establishing a low standard of patentability.[67] There are significant methodological challenges with measuring a court's performance - simply measuring the number of cases in which the patent holders won or lost is not telling anything, [68] if only because of selection effects and the fact that weak cases are dropped at an earlier stage without reaching an appeal. Similarly, Jaffe and Lerner argue that the standard of patentability established by CAFC is too low, but they fail to provide a clear cut definition of a "low quality" patent.[69] Almost inevitably, an assessment of CAFC (or any other court for that matter) to an extent relies on subjective perceptions and anecdotal evidence.

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59 For a very positive assessment of the Court's work, see Damon C Andrews, "Promoting the Progress: Three Decades of Patent Jurisprudence in the Court of Appeals for the Federal Circuit" (2011) 76(3) Missouri Law Review 839; the CAFC appears to enjoy a particularly good reputation at the bar, see e.g. Donald R Dunner, "A Retrospective of the Federal Circuit's First 25 Years" (2008) 17 Federal Circuit Bar Journal 127 ("...the court has more than delighted its early proponents and surprised its opponents with its high level of performance"), see further Dreyfus (n continuing), p 770 for a view that the CAFC is seen by the practitioners as an improvement upon previous litigation system.

60 Dreyfus (n 42), Gugliuzza (n 44).

61 Gugliuzza, (n 44), 1439

62 See Gugliuzza (n 44), 1494 for a view that it might be stifling innovation.

63 Rochelle Dreyfuss, "The Federal Circuit: A Case Study in Specialized Courts" (1989) 64(1) New York University Law Review 1, 26.

64 The FTC in its 2003 Report, "To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy", spoke of "questionable patents" being a problem for competition and innovation.

65 Baum (n 57), 1680.

66 Baum (n 57), fn 51.

67 Gugliuzza (n 44), p 1450. See Chad M Oldfather, "Judging, Expertise, and the Rule of Law" (2012) 89(4) Washington University Law Review 847, 850 ff for a discussion of the difficulty of reaching conclusions on the desirability or otherwise of specialisation.

68 Rochelle Dreyfuss, "In Search of Institutional Identity: The Federal Circuit Comes of Age" (2008) 23(2) Berkeley Technology Law Journal 787, 792, calling such attempts "naive".

69 See Dreyfuss (n 68), 794, pointing to the fact that the argument is based on anecdotal evidence.

22. Moreover, selected, widely talked about cases, such as *Kodak*[70] or *Xerox*[71] might have added to a patent-friendly perception of the court, even if they are not representative; or, conversely, they might be coinciding with a more general trend highlighting the importance of technology in the economy.[72] If this is the case, then perhaps CAFC is not as isolated as it is commonly believed and its case-law is just responding to the re-orientation of conventional thinking.[73] Even if we accept an argument that CAFC is offering stronger patent protection,[74] this does not provide us with a full picture of the situation, for if patent protection was insufficient previously, even a stronger influence of pro-patent groups today might mean an improvement of patent policy.[75] Part of the problem might be lack of a satisfactory yardstick against which to measure the Court's performance. While a perception of stronger patent protection does not allow for concluding that there necessarily exists a pro-patent bias, it still leaves questions about the balancing of interests in future cases.

23. Notwithstanding the problems associated with empirically measuring the impact of the potential risks involved, the way CAFC functions can still provide a valuable lesson for the impending UPC. The Federal Circuit was created for analogous reasons as the UPC: out of a belief that fragmentation of the patent system is damaging to innovation and the perceived need for uniformity.[76] Similarly, the creation of a Unitary Patent Court was among other things expressly justified by the need of uniformity and legal certainty in patent decision-making.[77] Doctrinal uniformity and predictability achieved through centralisation, however, might come at a cost. In case

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70 *Polaroid Corp. v. Eastman Kodak Co.,* 789 F.2d 1156 (Fed. Cir.) (upholding Polaroid's patent against Kodak's challenge).

71 *In re Independent Service Organisations Antitrust Litigation* 203 F.3d 1322 (Fed. Cir. 2000) (Xerox allowed to control the copiers after-market by refusing to deal with servicing companies).

72 And a coinciding re-orientation of antitrust policy favouring IPR expansion: Dreyfuss (n 63), 27.

73 Dreyfuss (n 63), 28.

74 As argued by Adam B Jaffe and Josh Lerner, *Innovation and its Discontents: How Our Broken Patent System is Endangering Innovation and Progress, and What to Do about It* (Princeton University Press 2004), p 126.

75 Baum (n 57), 1680.

76 Dreyfuss (n 68), 788; Gugliuzza (n 44), 1444.

77 European Commission Press Release IP/11/269 of 8 March 2011 "Patent Court: the Commission welcomes the delivery of the Court of Justice's opinion" ("The objective of the envisaged agreement, as it was submitted to the CJEU, is to set up a unified Patent Litigation System with a view to reducing the existing cost and complexity resulting from parallel litigation in several Member States and *providing legal certainty by avoiding conflicting judgments*." (emphasis added)); European Commission Press Release IP/13/750 of 29 July 2013 "Justice for growth: Commission fills legal gaps for unitary patent protection" ("The Court will be able to deliver judgments on the validity and the infringement of European and unified patents for all the Contracting States, avoiding parallel proceedings and *divergent outcomes*."(emphasis added)); European Commission Memo MEMO/12/970 of 11 December 2012 ("The single jurisdiction for patent matters will have the major advantage compared to today's situation that, in the future, legal certainty will be enhanced.").

of the CAFC, it seems to have pushed the court towards valuing precision of the rules over accuracy (understood as responsiveness to the philosophy of patent law as expressed in the legislative instruments, to national competition policies, and to the needs of innovators and innovation users).[78]

24. In fact, the judges sitting in CAFC have been very open about their lack of interest in policy creation. An outright refusal to consider the policy implications of their decisions might be in truth considered quite shocking, seeing how one of the judges has openly admitted that: "[N]ot once have we had a discussion as to what direction the law should take... We have just applied precedent as best we could determine it to the cases that have come before us."[79] Consequently, the decisions' reasoning often fails to consider the impact they will have on the patent system or on innovation. [80] If policy considerations are included at all, then they tend to take the form of "incantations of standard justifications for statutory terms",[81] rather than a real discussion.[82] In effect, CAFC has been accused of being formalistic in its approach. [83] Even though formalism, unlike bias, could in theory be defended as a legitimate approach,[84] a more economic policy-oriented approach has a lot to offer in the patent context, since it might allow for more industry specificity and flexibility in the approach.[85] In addition, a refusal to consider policy arguments can be seen "particularly inappropriate in a court established for the express purpose of orchestrating the development of patent jurisprudence."[86] Substantive patent law provisions are necessarily expressed in an abstract manner, leaving it to the courts to steer the meaning of terms such as "obviousness" or "technological invention". This way of writing the statute is inevitable since it is impossible to predict the form future inventions will take. The court is thus expected to be guided by the underlying

78 Dreyfuss (n 63), p 5.
79 As cited in Gugliuzza (n 44), fn 7.
80 Dreyfuss (n 68), p 803.
81 Dreyfuss(n 68), p 809.
82 The same criticism could be made of the Commission's decisions discussed in Part II, when referring to the impact of its decisions on the patent system.
83 See Arti K Rai, "Engaging Facts and Policy: a Multi-Institutional Approach to Patent System Reform" (2003) 103(5) Columbia Law Review 1035, 1103-1104 (including in cases at the antitrust-IP intersection).
84 ibid, 1115: "unlike bias, formalism is... eminently defensible as a normative matter."
85 See Christina Bohannan and Herbert Hovenkamp, "IP and Antitrust: Reformation and Harm" (2010) 51(4) Boston College Law Review 905, calling for a radical change of approach, requiring "IP injury", to make patent law more innovation-centred by limiting remedies to "situations in which the IP holder has suffered or is likely to suffer harm sufficiently linked to the purpose of IP law".
86 Dreyfuss (n 68), 791.

rationale of the patent system in making its decisions.[87] A bright-line rule based approach, applied by CAFC, foregoes this flexibility inbuilt into patent law, making it less accurate.[88] Plus, "ignoring, as an idea, the very idea that patents promote innovation"[89] does not make the law any more neutral, only less reflecting the goals of patent legislation.

25. Thus, precision and accuracy might be pulling in different directions.[90] It might also be that similar goals with which it was established will push the UPC in the same direction as the CAFC to value precision over accuracy in an attempt to create legal certainty. All in all, it is hard to explain CAFC's unwillingness to openly discuss policy implications of its decisions by the general mentality of the courts in the US, since in a common law tradition policy issues are usually very openly discussed in expansively reasoned decisions. To give just one example, the reasoning of the Supreme Court in *Actavis*, a competition case analysed in chapter 3, openly discussed the policy implications of the decision. It is rather the civil law tradition, followed in the majority of the European countries, which suggests a more restrained approach. Yet, perhaps, the need to establish its jurisprudence from scratch, on a basis of varying sources,[91] will push the UPC towards justifying its decisions in more detail. This would certainly be welcome, seeing that it could push the Court towards considering the innovation implications of its decisions in more detail.

26. The UPC's exclusive jurisdiction to hear cases concerning European patents and European patents with a unitary effect might also create isolationism through lack of exposure to competing views, which again might lead to bias. In this sense uniformity might also have its downsides, since exposure to competing views is said to increase the quality of the decisions. [92] This capture might be further strengthened by the influence of the highly specialised bar repeatedly representing its clients in cases before the UPC. On one hand, this risk might be offset by the fact that the UPC is not replacing national courts, which will remain competent to adjudicate on non-European

87 See Dan L Burk and Mark A Lemley, "Policy Levers in Patent Law" (2003) 89(7) Virginia Law Review 1575, arguing that patent law allows the court to develop patent policy by means of flexible legal standards which they call "policy levers".

88 ibid, p 1579.

89 Dreyfuss (n 68), p 819.

90 Dreyfuss (n 68), p 796.

91 Art 24, UPCA.

92 Craig Allen Nard and John F Duffy, "Rethinking Patent Law's Uniformity Principle" (2007) 101 North Western University Law Review 1619.

patents,[93] the independent voice of the EPO, and the divided structure of the court with its local divisions and an appeal court.[94] Also, the influence of the bar should not be magnified out of proportion, since they will be representing a variety of interests. Furthermore, the possibility of issuing dissenting opinions could add to the visibility of competing views.[95] On the other hand, the level of diversity today should not be overestimated. While the approaches to many issues vary across the Member States,[96] national courts tend to follow the lead of the EPO and also seek for consistency with each other when deciding parallel cases (as discussed in section II above). If the UPC manages to establish its position and take on a leading role as the patent court of Europe, taking over from the EPO,[97] then the level of diversity stemming from competing jurisdictions might turn out to be limited. Also, if the UPC turns out to be a great success, then the multinational composition of the judges of the UPC will with time not add to the exposure to competing views.

27. Still, the composition of the court might be of great relevance to the risk of isolationism. The UPC shall be composed of both legally and technically skilled judges.[98] The UPCA does not specify what background these judges should have,[99] but it is to be expected that they will be judges with at least some experience in patent law.[100] Closing the pool of legally trained judges to those with background solely in patent law might, however, contribute to the tunnel vision of the court. The UPC's Administrative Committee, responsible for the appointment of judges, might in that respect want to take the example of the English Patent Court of the Chancery Division (High Court) which has a varied composition, including judges with a background in competition law.[101] The composition of the Administrative Committee, thus, becomes

93 And in respect of issues falling outside the UPC's jurisdiction, Art 32(2) UPCA.

94 The Court is to be composed of the Court of First Instance (CFI) and a Court of Appeal. The CFI, in turn, is to be composed of a central division, with a seat in Paris and two sections in Munich and London (the division of responsibilities based on industry), and local or regional divisions in the contracting Member States (division of responsibilities based on the type of action).

95 Yet, it remains to be seen how often this possibility will be used. Art 78(2) UPCA talks of "exceptional circumstances" in which a judge of the panel may express a dissenting opinion, suggesting that the Agreement is not encouraging such course of action except on rare occasions of serious disagreement.

96 A widely discussed example is the question interpretation of claims, only partially resolved by art 69 EPC 2000, see Seville (n 10), 102 ff.

97 See above at para 8 ff.

98 Art 15(1) UPCA.

99 Art 15(2) UPCA.

100 Art 15(1) UPCA requires proven experience in the field of patent litigation, but then art 2(3) of the Statute annexed to the Agreement specifies that it can acquired by training under Article 11(4)(a) of the Statute.

101 At least two of the ten currently sitting judges have extensive experience of competition law. Mrs Justice Vivien Rose is a former Chairman of the Competition Appeal Tribunal and Mr Justice Peter

crucial, since an isolated Administrative Committee could be accused of making narrow appointments preferring judges from among its own field.[102]

28. Theoretically, the appointed judges might continue to receive some exposure to other issues by sitting in other courts, but it remains to be seen to what extent this opportunity will be used in practice.[103] Part-time specialisation could offer an advantage here, but it is not clear to what extent it will be used as the workload of the court increases.[104]

29. The UPCA also provides for a training framework for the UPC judges, which could potentially be a great opportunity for expanding the horizons of the otherwise highly specialized court. However, it appears from the language of the UPCA and the Statute that this training is aimed predominantly, if not solely, at patent law training in the strict sense. While article 19(1) states that a training network is to be established with the aim of improving and increasing available patent litigation expertise, which could be widely interpreted, article 19(2) proceeds at listing issues on which this training framework is to focus on and these are clearly related to patent law.[105] Furthermore, article 11(2) of the Statute lists ways in which exchange of expertise through training is to be achieved - it names *inter alia* cooperation with international organisations and education institutes, but limits it to the field of intellectual property.[106] So, while there is nothing in the wording of the UPCA or the Statute that would limit training strictly to patent issues, the aim of the training framework established by the Agreement was not to provide a widening of perspective, but rather to ensure (further) specialisation.

30. Yet, the Court might still be exposed to issues requiring knowledge going beyond patent law in the strict, formal sense. This is not only because, a balancing of innovation interests and competitive forces is inbuilt into patent rights as such, but also because competition issues arise before patent courts as so called 'competition

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102 Art 12 UPCA: the Administrative Committee shall be composed one representative of each Contracting Member State.

103 Art 17(2) UPCA specifies that legally qualified judges and full-time technical judges cannot engage in other occupation unless an exception is granted by the Administrative Committee, except for other judicial functions at the national level (art 17(3)). If at all used, it is likely that this option would be used to sit in panels also considering issues of patent law. Part-time technically qualified judges can take up other functions, unless a conflict of interests arises (art 17(4)).

104 See Baum (n 57), 1673 on the distinction between full-time and part-time specialisation.

105 The list is non-exhaustive, but with a clear patent focus: (a) internships in national patent courts or divisions of the Court of First Instance hearing a substantial number of patent litigation cases (c) technical aspects of patent law (art 19(2) UPCA).

106 Art 11(2)(b) of the statute to the UPCA.

defences'. An example of such case was *Huawei v ZTE* considered in chapter 6, which, although analysed as an antitrust case, arose out of a patent case. As noted by the Court of Justice, the UPC might be called to apply and interpret other instruments of EU law including rules of the TFEU concerning competition law in conjunction with which the Unitary Patent Protection Regulation would need to be read.[107]

31. The CAFC has initially took a wide interpretation of its jurisdiction in that sphere and was willing to entertain cases in which the patent law issue arose as merely a counterclaim.[108] This was seen as a positive development by some commentators,[109] since it expanded the Court's exposure to competition issues, and so to the economic and social background in which patents are operating, making it more likely that those considerations would be taken into consideration in other patent decisions. Others, however, were more critical, saying that CAFC's approach to antitrust matters overemphasised the IPR side of the equation.[110] Eventually, however, the Supreme Court in *Holmes*[111] limited CAFC's jurisdiction to cases in which the patent issue appears on the face of the well-pleaded complaint.[112] This means that a mere counterclaim of patent infringement in an unrelated action cannot form a basis for CAFC's jurisdiction.[113]

32. While doubts over the extent of CAFC's jurisdiction were entertained as a result of the ambiguity of the statute an in particular of the term "arising under", the situation of the UPC appears to be clearer. Article 32(1)(a) of the UPCA states that the UPC shall have exclusive competence over patent infringements and *related defences*, including counterclaims concerning licences. It will also have exclusive jurisdiction in counterclaims for revocation of patents and for declaration of invalidity of supplementary protection certificates.[114] Even though article 32(1)(c) speaks only of actions for provisional and protective measures and injunctions, it is to be expected

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107 Opinion 1/09 (2011) ECR I-01137, para 78.

108 *In re Independent Services Organizations Antitrust Litigation* (Fed. Cir. 2000) 203 F.3d 1322 (n 71) (CAFC entertaining jurisdiction over a refusal to license and so pronouncing on an antitrust claim in which a patent infringement counterclaim was raised). The decision has been criticised for giving little weight to anticompetitive concerns and favouring patent rights with the deterring effect on innovation: see for example Nicholas Oettinger, "In Re Independent Service Organizations Antitrust Litigation" (2001) 16(1) Berkley Technology Law Journal 323.

109 Dreyfuss (n 63).

110 See e.g. Gugliuzza (n 44), 1499, commenting on *Xerox* (n 71).

111 *Holmes Group Inc v Vornado Circulations Systems Inc.* (2002) 535 U.S. 826.

112 Dreyfuss (n 42), 787.

113 See Jiwen Chen, "The Well-Pleaded Complaint Rule and Jurisdiction over Patent Law Counterclaims: An Empirical Assessment of Holmes Group and Proposals for Improvement" (2009) 8(1) Northwestern Journal of Technology and Intellectual Property 94.

114 Art 32(1)(e).

that this should be interpreted to also cover related defences. Thus, the UPC will have considerable scope to shape competition policy. Any competition defences concerning SEP injunctions that might arise in the future as stemming from of the judgment in *Huawei v ZTE* might now become an issue for the UPC to tackle.[115] This might be a good development not only because it will increase the Court's exposure to the economic context surrounding the granting of patent rights, but also because it might be a body in a relatively good position to do the balancing of interests, equipped with more sophisticated remedies to answer competition problems arising in that area. It remains to be seen, however, to what extent it will use this opportunity and how well it will do it. Much depends on how the relationship between the UPC and the Court of Justice will develop.

IV Structural safeguards

33. Since the UPC Contracting Member States already have some experience with specialised patent courts,[116] one would expect that they would design the UPC with structural safeguards (i.e. elements of court design) against a risk of bias resulting from specialisation. The UPCA and its Statute, however, provide only a general framework for the establishment of the Court and a lot of details are left to be determined, be it through the rules of court or through practice. As things stand now, the design of the court does not ensure any particular structural safeguards to guard against the risk of bias, with the exception of the competence to hear competition defences as a means of exposure to the wider issues at play.

34. One of the mechanisms which could prove very useful in the UPC's enforcement practice is the use of *amici curiae* briefs. This tool is used very liberally by the

115 The situation opposite to a 'competition defence', i.e. a 'patent defence' in an antitrust action (*Xerox* (n 71) situation), however, might be more clearly seen as falling within the domain of an antitrust decision-making in the EU context, since the UPC is not part of the same legal order. Furthermore, the question of anticompetitiveness is usually seen as independent from patent status (which might vary from country to country). Taking the example of reverse payment settlements, it would be hard to imagine an antitrust action being stayed pending a resolution of the patent case (if only because according to the Commission the question of patent validity is not at issue in the reverse payment settlement context), or for the UPC to entertain jurisdiction over a private action for damages stemming from a reverse payment settlement simply because a patent defence has been raised (because in those circumstances it does not appear to be a *related* defence).

116 For example France, Germany, United Kingdom. In fact, over ninety countries have now experience of specialised IPR courts or tribunals: Rochelle Dreyfuss, "The EU's romance with Specialised Adjudication" (2016) IIC, 1.

CAFC.[117] It provides for a perfect opportunity for the court to hear a greater variety of views, going beyond expert views presented as evidence by the parties, providing for greater impartiality. Even though the tradition of *amici curiae* briefs has not been firmly established in the civil law tradition, it is not completely foreign to the courts. The Court of Justice has used its discretion in the past to allow for interveners in its cases, including in one of the decisions considered in part II, *Lundbeck*.[118] There is, however, a marked difference between allowing an intervener and an *amicus curiae*. The former, as opposed to the latter, has a vested interest in the judgment since the outcome might affect its rights even though it is a non-party to the dispute. *Amici curiae*, on the other hand, are often academics or associations active in the field that have no immediate interest in the case. In the American context, the liberal use of the mechanism allowed for greatly increasing the exposure of the court to different views. It would be interesting to see also the Commission's involvement in the UPC's proceedings to offer an antitrust perspective. It already has experience in offering written observations to national competition authorities under Regulation 1/2003 However, even if the Statute of the UPC does not prevent the Commission's involvement, following and engaging in the UPC decision-making would require a change of focus on the part of the Commission going beyond its direct sphere of competence.

35. Another way in which the UPC could guard itself from the risk of isolation is through accepting a wide variety of expert evidence. One of the ways in which CAFC's isolationism is expressed is through insulation from the use of extra-legal materials in its judgments. This is significant because it translates into a failure to consider the impact of the rules articulated by the court on innovation policy.[119] It could be that the court composed of specialist judges considers that it possesses a superior knowledge of the field through specialisation and consequently does not feel the need to refer to extra-legal sources to support its arguments. Even if ultimately it is the responsibility of the parties to present the evidence to the court, the court itself might encourage or discourage the lawyers representing the parties to put to it certain types of evidence. Inclusion of such context-building evidence in the court's reasoning not only sends a

117 Ryan Vacca, "Acting Like an Administrative Agency: The Federal Circuit En Banc" (2011) 76(3) Missouri Law Review 733, 743-744.

118 The intervener in that case was EFPIA (European Federation of Pharmaceutical Industries and Associations).

119 Dreyfuss (n 42), 782.

message to the parties about its importance, but also fleshes out the argument and allows to put it in its proper context, helping to justify the decision through the use of the underlying rationale of the patent system grounded in incentivising innovation.

36. Last but not least, as already mentioned above, the composition of the court might have important role to play in avoiding a risk of bias. The decision to include technically skilled judges in the panels along with the legally skilled judges was dictated by the often complex nature of the subject-matter. Yet, it is not the law that is complex but the factual technology context to which this law needs to be applied. If fact finding is left largely to the EPO and its Boards of Appeal, then perhaps there will be more need for judges with economic or commercial background rather than technically skilled judges. Having said that, technically skilled judges can also offer contextual knowledge by offering a better understanding of how particular industries operate. One way in which CAFC increases its exposure to differing court experience is to accept visiting judges. The effectiveness of this practice has been doubted though,[120] with the commentators pointing out that visiting judges can be quite deferential to the permanent judges,[121] costly, and disruptive to the collegiality of the court.[122] In any case, neither the UPCA nor its Statute foresee such possibility. Although the possibility of having part-time judges was probably included bearing in mind the limited workload of the Court in its initial days, it might serve the same purpose, without the disadvantages of one being simply a visiting judge pointed out above.

V Interaction between the UPC and the CJEU

37. Following a negative Opinion of the Court of Justice on an earlier version of the Agreement on the Unified Patent Court,[123] saying that it deprived national courts of the right to request preliminary rulings, such possibility was introduced into the UPCA.[124] According to article 38 of the UPC Statute, the procedures established by the CJEU for referrals for preliminary rulings are to be used, meaning that in line with article 267 TFEU, the UPC may refer questions to the CJEU where this is necessary

120 Gugliuzza (n 44).
121 Dreyfuss (n 68), 786.
122 Dreyfuss (n 68), 795.
123 Opinion 1/09 (2011) ECR I-01137.
124 Art 21 UPCA.

for giving a judgment and the Court of Appeal of the UPC is obliged to do so if this is the case. The Recital to the Agreement further specifies that the UPC must cooperate with the CJEU in properly interpreting EU law by relying on the latter's case law and confirms that the Member States are liable in damages for any breaches of Union law committed by the UPC, in particular a failure to request preliminary rulings from the CJEU.

38. The UPC will thus have to establish a working relationship with the CJEU. A possibility of having an external input on matters of competition law might be beneficial in terms of counteracting the potential for bias. However, it remains to be seen how willing the UPC will be to request preliminary rulings. Even though the Preamble to the Agreement contains a strong push for such requests to be made whenever necessary, the new UPC might want to establish its independent position by limiting the situations in which it will defer to the CJEU's guidance. This might be worrying especially if the UPC takes a wide stance on its competence to consider competition matters.

39. Either way, it needs to be pointed out that in any case the review afforded to the CJEU is very limited. Nearly all substantive patent provisions have been removed from the Regulation creating unitary patent protection, seemingly in attempt to prevent the CJEU's involvement in those matters. This has purportedly been caused by the mistrust in the ability of the Court of Justice to adjudicate on patent matters in a desirable way.[125] The more generalist input from the Court of Justice has thus been restricted.[126] This is despite the fact that article 262 TFEU provides for a possibility of conferring jurisdiction on the Court of Justice in disputes "relating to the application of acts adopted on the basis of the Treaties which create European intellectual property rights."

40. It is not inconceivable, however, that the Court of Justice will nonetheless try to assert a proactive position in respect of the new patent provisions. CJEU's jurisdictional record in creating EU law suggests just as much. Indeed, Jaeger suggests that Court proactivism is the only alternative to finding the Unitary Patent Regulation void, either

125 Petersen et al (n 28), p 41; Jaeger, (n 29), 391; cf Miłosz Malaga, "The European Patent with Unitary Effect: Incentive to Dominate? a Look From the EU Competition Law Viewpoint" (2014) 45 IIC 621 (explaining the removal of substantive patent provisions from the Regulation by Opinion 1/09 and the fact that it concluded that the Agreement would "alter the essential character of the powers which the Treaties confer on the institutions of the EU and on the Member States...").

126 Dreyfuss (n 116), 2.

because of lack of determinism or on grounds of primacy of EU law.[127] The Court's proactive stance could have unfortunate effects, however, in a situation where it is not given jurisdiction over substantive patent matters. This is because, again, it destines the Court to see just one side of the balancing act to be made. One is left to wonder whether it will show greater deference to unitary patents than in the early days of its jurisprudence when it showed a hostility towards patents.[128]

VI UPC and the EPO

41. Establishing a working relationship with other patent bodies will be even more complicated by the fact that there are already suggestions that practices of the EPO's Boards of Appeal and the CJEU are not consistent.[129] The nature of the relationship between the EPO and the UPC at the institutional level has not been yet clearly established. All that is clear is that the UPC is given a watch-dog function over the EPO by receiving the power to review its decisions.[130] The EPO itself might have a tendency for displaying a pro-patent bias. This is not only because, similarly to the UPC, it is also a specialised body entrusted with a particular mission, but also because it is self-funded. Reliance on renewal fees from patent holders might predispose it to an expansionist view on patentability. The risk of granting patent protection to questionable inventions is problematic because it unjustifiably closes off markets and negatively affects the balance between breakthrough and follow-on innovation. There might be thus a need to correct the already unbalanced vision of patent protection pursued by the EPO, but a fear is that it might only strengthen the tunnel vision of the UPC. Arguably, the EPO as an administrative body, equipped with specialised lawyers and patent agents, with many years of experience might be in a better position to decide on matters of patentability and indeed so far it has taken a leading role in shaping substantive patent law in Europe. This might lead the UPC to take a deferential stance to questions of patentability, especially when it comes to review of highly technical factual issues.

127 Jaeger (n 29), 391.

128 Valentine Korah, *An introductory guide to EC competition law and practice* (Hart Publishing 2004), 803-804; this early hostility could, however, be explained by the national scope of patent rights and the fact that they were consequently considered contrary to single market ideals by isolating national markets.

129 Petersen et al (n 28), 15.

130 Petersen et al (n 28), 41.

42. Even if the UPC proves to be proactive in revising EPO's decisions, it is not certain to what extent UPC revisions can instil a change of approach at the EPO, the membership of the EPC being much wider than that of the Unitary Patent Package Agreement. Until now the judicial control of the EPO has been limited, since the effect of national judgments on patent validity had only a national effect. It could be that UPC's revisions will be equally lacking in impact. Also, a narrower view on patentability taken by the UPC might push patent applicants to seek national patents instead, leading to a race to the bottom motivated by seeking of popularity of alternative modes of protection.

43. The UPC and the EPO might thus compete for supremacy as patent policy makers. Arguably, the EPO as an administrative body might be considered to be in a better position to do that job. All in all, the substantive patent law provisions are external to the unitary patent system and are contained mostly in the EPC, which can be amended only by the EPC members.[131] Yet, although the EPO has been taking a more pro-active stance in recent years in acting as a policy making body,[132] it is heavily under-resourced to face that task. The result might be a continuing dichotomy, hinging on a form of legal schizophrenia, in the European patent law and policy.

VII Conclusions

44. The fragmented nature of the patent system with institutions operating at different levels complicates the interaction between antitrust law and patent law. There exists no single body with which the Commission officials could work to improve the interaction between the two spheres of law. The Commission is expected to develop a close cooperation with the EPO concerning the functioning of the unitary patent system, but this is in respect of the practicalities of the functioning of the system rather than wider policy matters.[133] In the coming years, the EPO and the UPC are set to compete for the leading role as policy bodies responsible for patent policy making. Each of them has a role to play in developing patent law, EPO as an administrative

131 See Jaeger (n 29), 390 (pointing out that this solution has not been previously used in the EU and may well be incompatible with the primacy principle).

132 For example by getting involved in policy work together with EUIPO (formerly OHIM); see "Intellectual property rights intensive industries and economic performance in the European Union Industry-Level Analysis Report, A joint project between the European Patent Office and the European Union Intellectual Property Office" (October 2016, 2nd edn).

133 Art 14 Unitary Patent Protection Regulation.

body and the UPC as a judicial body. The problem is that they do not operate within the bounds of the same legal system affecting the same territory or patent rights. Thus, there is a risk of fragmentation and a persisting dichotomy of policies pursued. This makes the situation significantly different from the interaction of the Commission and the Court of Justice in the sphere of competition law.

45. Both the EPO and the UPC as highly specialised bodies are prone to displaying a pro-patent bias.[134] Specialisation might lead to insulation from legal problems and interests that would put the practices that are under scrutiny by that court in their proper economic and social context. Even though patent protection has an inbuilt balancing act within the rationale of the system, this might be insufficient to consider competition interests to their full extent. This is especially so, if the UPC in fulfilling its goals falls to the same traps as the American CAFC. [135] Excessive formalism might prevent the UPC from considering policy implications of its decisions which might be harmful to innovation. Exposure to competition defences, on the other hand, might aid the situation and open the court to the wider context at play.

46. The design of the UPC does not have any particular inbuilt structural safeguards that would guard against the risk of pro-patent bias. If anything, the selection of judges and the design of the training framework established under the UPCA might strengthen the risk of such bias by furthering even stricter specialisation. It could be thus argued that the impeding Brexit, which might necessitate the re-opening of the UPCA might be a good opportunity to revise the issue of structural safeguards.[136] It might be, however, that it would be like re-opening of the Pandora box, which is something that all the participating Member States might want to avoid. Taking this political reality into account, the loosely built design of the UPCA might be used to include such structural safeguards without a re-opening of the Agreement. All in all, there appears that there

134 Similar criticism could be made in respect of the Commission displaying an opposite pro-competition bias in its antitrust decisions - as explored in Part II. Cf Rifkind (n 56), 426 distinguishing between judicial and administrative bodies and their respective roles: ("On the administrative level there is advantage to be derived from close familiarity with the pattern of activity which is the subject of administrative action and regulation. The very essence of the judicial function, however, is the detachment from, a dispassionateness about the activity under scrutiny."; similarly, see Jordan (n 40), 764 ("the line between courts, designed to resolve disputes and consider competing concerns, and agencies, defined and informed by their mission, must be maintained.").

135 Cf suggestion by Dreyfuss (n 63), 67 that the lessons learnt from CAFC's experience might not be transferable.

136 One of the sections of the central division of the CFI of the UPC is to be located in London. This localisation is specified in the UPCA itself (art 7), but it might no longer be considered justified if the UK leaves the EU.

is nothing in the wording of the Agreement that would prevent, for example, the introduction of *amici curiae* briefs through the Rules of Court.

47. The UPC might be a great opportunity for streamlining patent policy. After all, it provides a chance for grant and enforcement issues to be considered by a single body, which should lead to a more uniform policy approach. At the same time, the creation of the specialised Unitary Patent Court is riddled with challenges. If one does not stay attentive to the underlying rationale of the patent system and its influence on shaping the conditions of competition, it might be that centralisation "might do nothing to promote the development of a patent law that is sensitive to innovation policy."[137] While the risk of a pro-patent bias appears to be a real possibility, strengthening of the approach to issues arising at the patent-antitrust intersection as seen from the innovation perspective might require a careful management of such risk. The existence of a risk of biases on either side might mean that an outcome of a case might depend on which field of law is used to address it.

[137] Gugliuzza (n 44), 1494.

Chapter 10
Strengthening the process - the way forward

I Introduction

1. Part II analysed the case studies to see what problems the European Commission and the CJEU might encounter with the application of antitrust to cases raising patent issues and whether these problems could potentially be alternatively solved through patent law. It was visible that in applying antitrust law the competition authorities are at risk of displaying a pro-competition bias. Previous chapter, on the other hand, showed that the forthcoming UPC is at risk of exhibiting an opposite pro-patent bias. Both of these cognitive biases might work to prevent an appropriate balancing of interests at play to the detriment of innovation.
2. When simply looking at the outcomes of the cases discussed in part II, it is hard to conclusively state whether they are examples of such bias, if only because such biases are inherently difficult to measure. What one may perceive as a pro-competition decision, another might view as a pro-patent decision. In any case, outcomes of those few cases that have come to the attention of the Commission in the past few years could only be taken as anecdotal evidence of the existence of such biases. The focus here, however, is not on the outcomes of individual cases, but rather on the decision-making process that leads to those outcomes. In this way, to an extent the measurement problem can be avoided. Hence, one does not need to search for an objective standard of what is a pro-competition and what is a pro-patent decision. More importantly though, focusing on the process makes more sense if one wants to find ways of improving enforcement in the area. By finding ways to improve reasoning underlying the decisions by providing input that now might be lacking (as strongly suggested by the analysed cases), one can hope to achieve more balanced results in the future. Those more balanced outcomes in turn should reinforce and influence the deliberation process in future cases, for at the end of the day outcomes and the reasoning process that leads to them are inseparably intertwined.
3. Having analysed possible problems at the antitrust-patent intersection, this chapter concentrates on the ways in which the decision-making process can be improved. It is argued here that separate treatment of matters that arise at that intersection contributes

to the emergence of biases in the decision-making process (section II). Lack of interaction leads to insufficient exposure to certain arguments which in turn leads to them being undervalued. It would appear that evidence as presented by the parties is insufficient to open the eyes of the Commission to the trade-offs that are being made in competition decisions, leaving them without proper consideration. To widen the Commission's perspective an external input might be needed.

4. Yet, despite the fact that the antitrust-patent intersection is being subject to separate treatment, a look at the reasons why antitrust authorities intervene in certain patent issues suggests that this might be done with an intention to signal to the patent authorities that patent policy is ailing in certain areas (section III). Criticism of patent policy (both implied and explicit) in antitrust decisions can be taken as a call for patent authorities to spring into action. Thus, signalling might be taken as a mechanism that breaks away with the separate treatment (or indeed arises out of it). If successful, it should eventually reduce the need for antitrust intervention to novel cases. Yet, as novel issues are bound to arise, signalling back might serve to reduce the pro-competition bias in antitrust decision-making (section IV). In this way a real interaction between antitrust and patent policies might be established. Still, as this form of interaction is an imperfect one, this chapter urges establishing greater cooperation outside enforcement (section V). If need be, this might take a more formalised form. Communication between competition and patent authorities outside enforcement might be very useful in combating the potential for a pro-patent bias on the part of the patent authorities by sensitising them to competition issues that might arise in the patent context. A comparison with the US practice in this sphere might serve as a useful example. Finally, it has to be acknowledged that the particular institutional set up of the European institutions, with fragmented patent authorities in particular, might become a limitation on establishing an effective working relationship policy that can work well towards a unified innovation policy between these two fields of law (section VI).

II Separate treatment as a source of problems

5. Antitrust cases discussed in Part II of this thesis show that insufficient consideration of the patent side of the issues raised therein, resulting in part from separate treatment of antitrust and patent policies, might lead to a pro-competition bias which might be harmful to innovation. Similarly, a high-level of specialisation and relative isolation of the patent courts, and in particular of the forthcoming Unitary Patent Court, might lead to an opposite pro-patent bias. Although both competition and patent law systems have inbuilt mechanisms to consider the innovation implications of their respective decisions, a court or an administrative agency seized of the case might still lack in perspective to become a platform capable of ensuring an adequate balancing of interests at play.
6. This can be in part explained by the fact that the Commission is acting as a specialised competition agency in deciding cases before it and so it is seized of a potential competition matter and not of an innovation problem. This distinction can be of paramount importance. Even if pursuing or fostering innovation is one of the objects of antitrust law, naturally an antitrust agency will have a preference for applying a competition law solution to the problem put before it. Quite obviously this is so because it is the only mechanism it has at its disposal to tackle it. However, if in doing so it downplays or ignores the justifications for the conduct that are grounded in the rationale of the patent system, the situation becomes problematic. The same can be said of a situation where the impact of an antitrust decision on the patent system becomes a mere side-effect that is not considered as part of an antitrust decision. In doing so, the Commission risks ignoring the multifaceted nature of the competition process, which includes competition in innovation which is enabled by the patent system. Thus understood inbuilt preference for innovation through competition rather than exclusivity is the essence of the pro-competition bias. The danger involved in such situation is that it might undermine the incentives to innovate.
7. Equally, national patent offices and the EPO are prone to display an opposite pro-patent bias, favouring innovation through exclusivity. Incentivising innovation by creating a reward mechanism that is meant to create a race in innovativeness can be seen to be the very nature of the patent system. Thus, balancing of various interests, including those of breakthrough and follow-on innovators, and creation of competition lies at the heart of patent policy. It could be thus seen as the primary platform for the

balancing exercise to be made to accommodate different modes for incentivising innovation. Yet, when it comes to enforcement, these paramount policy issues are hardly ever discussed directly, but rather through the concepts of patent law such as obviousness or other patentability requirements.[1] Operating through those concepts, naturally more familiar to patent lawyers, does not necessarily lead to avoidance of the balancing exercise, since those involved in their interpretation should be appreciative of their significance and the real commercial impact a narrow or a wide approach to, for example, the question of patentability might have. Nonetheless, formalism in the analysis and concentration on technical details pertaining to those concepts might lead to losing sight of the policy issue at the heart of the problem. This, compounded with limited exposure to non-patent issues that would sensitise patent authorities to commercial reality and the conditions in which competition occurs, might lead to favouring of 'patent solutions' as a way of incentivising innovation. Thus expressed pro-patent bias can provoke unjustified patent expansionism, which might in fact turn out to be harmful to innovation.

8. These two potential biases are in part a problem stemming from separate treatment of antitrust and patent law that ignores the other side of the "innovativeness equilibrium" that requires a careful balance to be established between "the carrot and the stick" in form of respectively patent exclusivity and pressure formed through competition. In effect, patent law and antitrust law might each be pulling in the opposite direction, undermining each other rather than complementing each other. These problems are not necessarily meant as a critique of the officials working for the Commission or the European patent officials. The pro-competition and the pro-patent biases to which the respective authorities might fall are, in fact, typical for any field of law that is entrusted to a distinct administrative agency. They might be a result of a combination of various cognitive biases, such as a mere exposure effect,[2] focusing effect,[3] or a problem associated with framing.[4] Equally, in deciding to get involved, antitrust

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1 A simple key word search of the EPO Boards of Appeal decisions does not bring up any relevant results in connection to the competition process or incentivising innovation.

2 Also known as the familiarity principle, a type of cognitive bias by which people display a preference for things they are more familiar with; see Robert B Zajonc, "Attitudinal Effects of Mere Exposure" (1968) 9(2) Journal of Personality and Social Psychology 1-27; Robert B Zajonc, "Mere Exposure: A Gateway to the Sublimal" (2001) 10(6) Current Directions in Psychological Science 224.

3 Denoting a tendency to give too much importance to one aspect of a situation over others; see Adrian Furnham, Hua Chu Boo, "A literature review of the anchoring effect" (2011) 40(1) The Journal of Socio-Economics 35-42.

4 A framing effect concerns a situation where the same set of information leads to different conclusions depending on how that information is presented; see Irwin P Levin, Sandra L Schneider and Gary J

authorities might be said to be using antitrust as a Maslow's hammer.[5] As discussed in the previous chapter, high level of specialisation on the part of the patent authorities might also lead to regulatory capture. Even if not caught by regulatory capture, antitrust authorities and patent authorities alike might still be subject to *déformation professionnelle*,[6] meaning that they are likely to see things through the lens of their own profession rather than from the wider perspective, which in this case is the innovation perspective.

9. Although those behavioural biases are not specific to antitrust or patent policies, the way in which they demonstrate themselves in this particular context might be said to be particularly significant because of the specific relationship between those two sets of laws. The peculiarity of the present situation can be ascribed to the fact that both of the discussed sets of laws are said to be furthering a common objective, i.e. promotion of innovation. Taking the innovation perspective as the starting point, the imperfect relationship between antitrust and patent law based on separate treatment becomes problematic. Separate treatment increases the risk of the biases described above and limits the chances for establishing a platform where different innovative interests are considered in a balanced manner. As discussed already in chapter 2, this balancing is crucial if we assume that both the pressure from competition and the lure of patent exclusivity as creator of a Schumpeterian race are both components of an innovative environment.

10. Régibeau and Rockett, who are proponents of a separate approach, point out, on the other hand, that IP and antitrust law should be separated by design and confined to their respective roles.[7] In case of patent law its function should be to properly assign and defend property rights, while competition law "should be concerned with the *use*"

Gaeth, "All A simple key word search of the EPO Boards of Appeal decisions does not bring up any relevant results in connection to the competition process or incentivising innovation.

4 Also known as the familiarity principle, a type of cognitive bias by which people display a preference for things they are more familiar with; see Robert B Zajonc, "Attitudinal Effects of Mere Exposure" (1968) 9(2) Journal of Personality and Social Psychology 1-27; Robert B Zajonc, "Mere Exposure: A Gateway to the Sublimal" (2001) 10(6) Current Directions in Psychological Science 224.

Frames Are Not Created Equal: A Typology and Critical Analysis of Framing Effects" (1998) 76(2) Organizational Behavior and Human Decision Processes 149-188.

5 Also known as the law of the instrument, as expressed by Abraham H. Maslow, *The Psychology of Science: A Reconnaissance* (Maurice Bassett Publishing 1966), p 15: "...it is tempting, if the only tool you have is a hammer, to treat everything as if it were a nail."

6 As used by Daniel Warnotte, "Bureaucratie et fonctionnarisme" (1937) 17 Revue de l'Institut de Sociologie 245-260.

7 Pierre Régibeau and Katharine Rockett, "The relationship between intellectual property law and competition law: an economic approach", ch 10 in Steven D Anderman (ed*), The Interface between Intellectual Property Rights and Competition Policy* (CUP 2007), p 505.

of those rights.[8] However, this approach has some shortcomings. First of all, the distinction between use and existence of a right can be seen as artificial and impossible to delineate in practice. After all, of what is a patent right composed if not of the use that right? Deciding what rights patent exclusivity actually confers is at the core of substantive patent law provisions.[9] Equally, refusals to license are a matter for both patent law and antitrust. Substantive patent law includes provisions on compulsory licensing and yet refusals to license have been at the forefront of the *Microsoft* case even though at first sight such activity would appear to be the very essence of the existence of a patent right. Furthermore, the answer to which field of law is better suited to deal with, for example, unjustified threats of litigation or misrepresentations to the patent office is not in the least clear, as the discussion in Part II has shown. This indicates that the functions of antitrust law and patent law are not completely separate. Régibeau and Rockett note that antitrust and patent law tend to "intervene at different stages of the economic life cycle of an asset."[10] Yet, this is not a necessary conclusion. Some of the cases ending up before the CJEU as antitrust cases originate as patent cases in which a competition defence has been raised, as can be illustrated by *Huawei v ZTE* discussed in chapter 6. Admittedly, antitrust law has little or no interest in the majority of patent cases, which, at least on the face of it, do not raise competition issues. Yet, these cases form the conditions of competition that can be later considered by antitrust authorities. One of the implicit criticisms of the patent system made in the context of reverse payment settlements (chapter 3) related to the quality of the patents granted and the shape of patent litigation which could be seen as facilitators of those unwanted settlements.

11. Secondly, at least at first sight, an approach based on separate treatment appears to ignore the impact one field of law has on the other and vice-versa. To the contrary, Régibeau and Rockett observe that an optimal patent policy would need to change in accordance with the approach taken by the competition authorities.[11] While they acknowledge the fact that antitrust and patent law have a joint impact on the incentives to innovate, they still consider that this does not create a need for explicit

8 ibid.

9 As evidenced by TRIPS, arts 28-31, or EPC art 64.

10 Régibeau and Rockett (n 7), p 522.

11 Recognising that the approach taken by antitrust law influences the level of the reward obtained through patent law (pp 514-515, relying on studies by Gilbert and Shapiro (RJ Gilbert and C Shapiro, "Optimal Patent Length and Breadth" (1990) 21(1) Rand Journal of Economics 106) and Green and Scotchmer (JR Green and S Scotchmer, "On the Division of Profit in Sequential Innovation" (1995) 26(1) Rand Journal of Economics 20-33) to support the argument).

cooperation.[12] In fact, the opposition to a more unified treatment of antitrust and patent law seems to be stemming from the fact that it creates a temptation on the part of the Commission to revisit the trade-off between creating the incentives to innovate and the resulting inefficiencies already made as a matter of patent policy.[13] Yet, it would seem that to an extent this is unavoidable if antitrust is to get involved in patent matters (and Régibeau and Rockett argue that it should)[14]. Any decision that impacts patent law beyond the reach of an individual case will involve a re-evaluation of the trade-off previously made as a matter of patent law (we have seen examples of such rebalancing in Part II). It is rather lack of an open discussion about the trade-off made that is the cause of problems.

12. It is argued here that separate treatment does not eliminate trade-offs between static and dynamic efficiencies or breakthrough and follow-on innovation. Rather, at best it obscures them from sight and more likely it prevents an open discussion of the impact a decision might have and creates a greater risk of biases in the decision-making process. In this way separate treatment might enhance the potential for conflict between antitrust and patent policies. This is so because in this way one may develop a tendency to view separate functions of antitrust and patent law to mean that the former should be concerned only with static competition and the latter to neglect its "competitive philosophy"[15].[16] This limited understanding of the roles played by patent law and antitrust law reinforces a view of conflict, since in this way these two sets of law are pulling in the opposite directions. Indeed, a greater involvement of both antitrust and patent authorities in the policy issues at the borderline of patent and antitrust law should increase the awareness of the multifaceted nature of the problems at hand. This could, perhaps, spur a greater deference to the trade-offs made by the patent authorities and more competition oriented trade-offs on the part of the patent authorities in the first place.

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12 Régibeau and Rockett (n 7), p 521.

13 Régibeau and Rockett (n 7), pp 522-523.

14 They argue that there is "no need to treat monopoly power based on IP as 'special'" (p 505), but at the same time they state that competition policy in the area should develop following a set of principles, including 'restraint' and a 'commitment not to revisit' the rights granted by IP law (p 525).

15 Valentine Korah, *Intellectual Property rights and the EC Competition Rules* (Hart Publishing 2006), p 1.

16 Cf Régibeau and Rockett (n 7) p 523, who do not consider that a trade-off between static and dynamic efficiency should be part of competition law analysis.

III Signalling as a way to reduce the need for antitrust involvement

The 'if' question: lack of a standard that would allow for an effective filtering of cases subject to antitrust enforcement

13. The shape of antitrust application to patent matters is intertwined with the question that comes prior to the question 'how' it is supposed to look like, which is whether it should take place at all (the 'if' question). For the large part, the ongoing discussion concerning that question so far centred around the question of formal competence. The disagreement concerns the issue whether patent rights should be treated in a special manner or simply as a species of monopoly.[17] Over the years, the attitude of the courts and administrative agencies varied from a position of total patent immunity to that of complete competition dominance.[18] In Part II we have seen the Commission and the Court applying various tests for delineating the reach of antitrust involvement. In case of reverse patent settlements it was a test based on the "subject-matter of the patent" which was said to be akin to the distinction based on existence and exercise of a patent (resonating the separate treatment approach advocated by Régibeau and Rockett). In the *AstraZeneca* case, in turn, the existence-exercise dichotomy was rejected in favour of the "competition on the merits" approach. The same approach was also used in the decisions concerning standard essential patents, though it was also complemented by the "exceptional circumstances" test borrowed from *Microsoft*.

14. None of those tests, however, provides for an effective mechanism that would allow for delineating the sphere of competition competence or indeed justify it in terms other

17 The answer to that question might in part depend on how one views patents: as rights or as a species of property. While the official line in the US likens intellectual property to any other form of property (US Department of Justice and the Federal Trade Commission, "Antitrust Guidelines for the Licensing of Intellectual Property'", 12 January 2017, p 2; many scholars counter that position. Drexl for example calls for a differing treatment of intellectual property based on its specific economics (Josef Drexl, "Is there a more 'economic approach' to intellectual property and competition law?", in Josef Drexl (ed), *Research Handbook on Intellectual Property and Competition Law* (Edward Elgar 2008), pp 49-50). Correspondingly, Ghidini points to lack of inbuilt limitations ("duties grounded in social welfare") in intellectual property akin to servitudes in real property - for him antitrust intervention is achieving that effect from the outside where it cannot be achieved from the inside (Gustavo Ghidini, "The Bride and the Groom. On the Intersection between Intellectual Property and Antitrust Law", in Giandonato Caggiano, Gabriella Muscolo and Marina Tavassi (eds*), Competition Law and Intellectual Property: A European Perspective* (Kluwer Law International 2012), p 44.). Régibeau and Rockett (n 7), on the other hand, draw on the similarities between real property and IP (p 508).

18 The EU approach has always been more interventionist compared to the US experience, see Valentine Korah, "The interface between intellectual property and antitrust: The European experience"(2002) 69(3) Antitrust Law Journal 801; Herbert Hovenkamp, "IP and Antitrust Policy: A Brief Historical Overview" (December 2005) University of Iowa Legal Studies Research Paper No 05-31.

than bordering on the arbitrary. A closer look at each of those tests shows that they all lack in analytical vigour to make them workable standards. Starting off with the distinction between existence and exercise that originates from *Consten v Grundig* case concerning a trademark,[19] it immediately becomes visible that it is a bit of an intellectual stretch. While it could be argued that it made some sense in the particular context of that case, where a trademark's existence could be meaningfully distinguished from the use to which it was put by the trademark owner, where that use did not simply concern putting it on the product to distinguish it from other products, but using it in a distribution agreement as a way of obtaining exclusive licensing, it is much more difficult if not impossible to use it in the patent context. In case of patents it is even more difficult, if not impossible, to meaningfully distinguish between existence and exercise of a right, since the very essence of the right consists of the right to exclude and nothing beyond that. As a matter of pure logic, the distinction becomes hard to sustain - the existence and exercise of a patent are inseparably intertwined. Having been subject to heavy criticism,[20] it appeared for a while that the distinction has been quietly abandoned by the Court after a period of regular use.[21] Yet, as the *Servier* case has shown, the test has not become obsolete, despite the fact that it posed the same kind of problems in the reverse payment settlement context.

15. Moving on to the competition on the merits test, it suffers from the same problem.[22] Although in theory it allows for distinguishing between conduct which results from the "normal" use of the patent rights and anticompetitive conduct, it is based on the competition's authority understanding of what constitutes "normal" use. Despite being

19 Joined Cases 56 and 58/64 [1966] ECR 299; see David T Keeling, *Intellectual Property Rights in the EU: Free movement and Competition Law* (OUP 2003), vol 1, p 50 ff for a discussion of the dichotomy between the existence and exercise of a right.

20 Valentine Korah, "Dividing the Common Market through National Industrial Property Rights" (1972) 35(6) MLR 634, 636: "a right cannot consist of more than the various ways in which it can be exercised. The distinction between a right and its exercise, since it is not defined, and cannot be applied by logical analysis, confers a free discretion on the tribunal drawing the distinction in particular instance"; René Joliet, "Patented Articles and the Free Movement of goods within the EEC" (1975) Current Legal Problems 15, 23: "the distinction... appears... of doubtful validity"; cf Roberto Casati, "The 'Exhaustion' of Industrial Property Rights in the EEC: Exclusive Manufacturing and Sales Provisions in Patent and Know-how Licensing Agreements" (1978) 17(2) Columbia Journal of Transnational Law 313, 321 ff; J Mertens de Wilmars, "Aspects communautaires du droit des marques" (1972) 87 Journal des Tribunaux, No 4806.

21 Keeling (n 19), p 55; cf G Marenco and K Banks, "Intellectual Property and Community Rules on Free Movement: Discrimination Unearthed" (1990) EL Rev 224, 226.

22 See OECD, "Competition on the Merits" (2005) DAF/COMP(2005)27, available at https://www.oecd.org/daf/competition/abuse/35911017.pdf (accessed 20 January 2017), p 9 stating that the continued use of the term without a generally accepted definition has "led to inconsistent interpretations, and therefore to unpredictable results".

premised on the separate treatment and patent immunity approaches, it requires the competition authorities to delineate the scope of use prescribed by patent law. In effect, this could be said to be bringing the competition on the merits test close to that based on "scope of the patent" recently rejected in the US in the *Actavis* case (as discussed in chapter 3). The US scope of the patent approach, just like the "competition on the merits" standard, was based on the idea that antitrust and patent law concern two distinct spheres. While the scope of the patent test was invented specifically with delineation of competence between antitrust and patent law, the competition on the merits test has been used by the CJEU more widely also outside the IPR context and was then equally criticised for vagueness.[23]

16. Similarly, by its very name the "exceptional circumstances" test is not prone to logical explanation, since it is left to the Court to decide on a case-by-case basis why a normal rule should not be followed. Thus, it is just as much unpredictable as the tests discussed above. While it could be argued that it has the advantage of taking non-intervention as a default position, in practice this conclusion depends on how widely one defines 'exceptional circumstances'. What do all those tests have in common, however, is an idea that antitrust should intervene only in cases going beyond the ordinary use of patent rights prescribed by patent law and that there is a certain core of patent policy with which antitrust should not interfere with or curtail.[24] It could be seen simply as a sign of formal division of competence, but perhaps it is also an implied recognition of the value of the patent right mechanism and the fact that antitrust law should not interfere with patent rights to the extent that would destroy the principle upon which it is built. So, in substance all of the legal tests used by the Commission and the CJEU are not that different. In each case the level of intrusiveness of competition law into patent law depends on how deferential the authorities are willing to be to the arguments that an activity comes within the nucleus of the patent right and how widely that concept will be construed. All of those tests are meant to justify antitrust involvement in the formal sense, but do not explain what

23 See e.g. Case C-209/10 *Post Danmark A/S Konkurrencarådet* ECLI:EU:C:2012:172; Alison Jones and Brenda Sufrin, EU Competition Law (OUP 2014, 6th edn), p 363 ("the concept does not provide a tool for objectively drawing a line between 'good' and 'bad' conduct in the middle").

24 With patent holders creating new strategies for exploiting patent rights the understanding of what constitutes 'ordinary use' might change over time.

form it will take.[25] They are not grounded in any economic justification why antitrust law (and not patent law) is (best) suited to deal with the matter.

17. Is it possible then to define with any level of specificity the circumstances in which antitrust law is being applied to patent matters? If one looks at the theory of harm pursued in each of the cases discussed in Part II, it appears to be specific to each individual situation. The common type of harm can only be defined in the broadest terms as abuse of the patent system and that does not tell much. In each scenario, antitrust appears to intervene when patent law does not provide a solution or when a solution it provides does not appear to be sufficient. In this sense, antitrust could be seen as a second filter tending to the problems with patent policy which it has not fixed itself.

18. Although Régibeau and Rockett suggest that antitrust involvement comes at a different point in time in the patent's life cycle than in the case of it being handled by patent authorities,[26] it would appear that this is not necessarily a defining feature that would help explain the circumstances in which one could expect antitrust involvement. As discussed in Part II, *AstraZeneca* case concerned an early stage in the patent's life cycle (pre-grant),[27] while SEP and RPS cases concerned patent litigation concerning already existing patents. The distinction between 'assigning and defending' of patent rights and their 'use' might not be thus not easy to sustain, at least in temporal terms.

19. Is it then that antitrust works as a repair-it-all mechanism? If one looks at the circumstances in which cases reach the Commission and the Court, it cannot be said that the Commission is necessarily always acting like an "overeager policeman." Broadly, one can distinguish two different sets of circumstances in which the issues involving patents are put to the attention of the EU competition authorities. First, there are cases which reach the Court in form of requests for preliminary rulings, like for example *Huawei v ZTE*. In those actions the competition issue can be raised as a "shield", i.e. a defence in a patent case. The Commission has no control over those kind of cases. Even though national (patent) courts might be seeking the CJEU's guidance, ultimately it is up to them to decide the case before them. Even though in those circumstances the Court might also decide that an issue is not an antitrust

25 In fact, Casati views the distinction between existence and exercise as one akin to the supremacy principle: Casati (n 20), p 323.

26 Régibeau and Rockett (n 7), p 522.

27 SPCs are treated as akin to patent rights here.

concern,[28] the issue of prioritising does not come into the picture in those cases. The second kind of cases are decisions made by the Commission itself in which it condemns a practice (under article 7 of the Regulation1/2003, like for example the *Samsung* decision) or accepts commitments following an investigation process (under article 9 of the Regulation 1/2003, like for example the *Motorola* decision). In those circumstances, antitrust is acting as a "sword" and the decision whether to use that weapon lies with the Commission. SEP context shows that the same issue can be considered by the competition authorities acting both as a "sword" and a "shield".

20. When the Commission is using competition law as a "sword", it is up to it to decide whether it is the correct tool to use and whether antitrust involvement is justified. It is in those cases that the Commission might be using antitrust as a 'repair-it-all' mechanism. The Commission has a greater scope for actively developing the direction in which antitrust is to go in its enforcement ever since the Modernisation Regulation abolished the notification mechanism. One can look to soft law instruments, such as guidelines on the applicability of Article 101 of the Treaty on the Functioning of the European Union to horizontal co-operation agreements [29] or the corresponding guidance on the Commission's enforcement priorities in applying Article 82 of the EC Treaty to abusive exclusionary conduct by dominant undertakings,[30] to try to decipher what sort of situations are likely to interest the Commission. These instruments, however, provide guidance which is largely based on already existing precedents and are of limited value when it comes to trying get a sense of the actual direction of future antitrust enforcement practice. These soft law instruments are also not IPR specific - they contain only few passages which relate specifically to IPR problems, most notably on the question of refusal to licence [31] and standard setting in the IPR context.[32] They are thus insufficient to figure out the key to antitrust enforcement in the patent context.

21. Many cases come to the Commission as complaints from market players, but it is a matter of the Commission's priorities to decide which cases to take up. Whether or not an investigation is initiated following a complaint or at the Commission's own initiative, like any competition authority it needs to be guided by some practical

28 As it happened in Case C-567/14 *Genentech Inc. v Hoechst GmbH and Sanofi-Aventis Deutschland GmbH* ECLI:EU:C:2016:526.
29 2011/C 11/01 (art 101 Guidelines).
30 2009/C 45/02 (art 102 Guidance).
31 Art 101 Guidelines, para 75 ff.
32 Art 102 Guidance, para 257 ff.

considerations in selecting cases to pursue, not least because of the need to effectively use the limited resources it has at its disposal. A speech from Commissioner Vestager concerning setting of priorities in the antitrust context seems to be confirming generally held views on the rationale of case selection.[33] In selecting the most important cases DG Comp guides itself by the impact the decision will have. This justifies concentration on some of the key sectors that have an impact on the whole of the economy. Thus, an interest of the Commission in certain sectors as expressed by the sector inquiries might be a good hint for the direction competition enforcement is likely to have. Experience has taught us that the Sector Inquiry into the Pharmaceutical Sector, discussed in Chapter 5, was soon followed by investigations to some of the practices described in the report, as evidenced by the *Lundbeck* and *Servier* decisions. The Commission is set to select cases that are likely to have an impact beyond the case itself. In setting precedents it aims at steering compliance, induce deterrence and provide guidance on antitrust principles applicable to novel situations (interestingly, Commissioner Vestager used an example of *Motorola* and *Samsung* decisions as an example of such case).[34] It also has to decide whether competition law is the right tool for the job. Unfortunately, guidance on how it is decided that antitrust is the right tool for the job is scarce beyond repeated statements that it has to be a competition problem. Seeing that impact is one of the key ingredients in selecting cases subject to enforcement, it is argued here that there might be one more, less explicit, reason for selecting certain cases, which is that of *signalling*.

Signalling

22. As already stated above, the impact of a decision should be measured by the influence it has beyond the individual case at hand. In issuing its decisions the Commission sends a signal to the market players about the need for compliance and provides guidance on the way competition law should be interpreted (though subject to CJEU's position on the matter). Yet, what if the signal that it sends is not directed solely at other market players, but also at other regulatory institutions? The criticism levelled against the way patent system is functioning as seen in the decisions analysed in Part II could be interpreted as encouraging patent institutions to change the way they work

33 Margrethe Vestager, "Setting priorities in antitrust", Speech of 1 February 2016, available at https://ec.europa.eu/commission/2014-2019/vestager/announcements/setting-priorities-antitrust_en (accessed 15 January 2017).

34 ibid.

and/or invite legislative change. The idea that patent policy should adapt to fluctuations in competition policy approach is not new. However, it relates to general shifts in competition policy approach as affecting the size of the reward that go beyond individual cases. Instead, it is submitted here that individual cases might also have a shaking up effect or at least be intended to create such an effect in respect of patent mechanisms that are ailing or are non-existent.

23. It is a characteristic feature of the European legal order that various agencies do not operate all at the same level as not all of the areas of law are harmonised and subject to central policy making. Due to these institutional limitations, at times, establishing informal tunnels of cooperation between various agencies responsible for different branches of law might be difficult. This is exactly the case with the relationship between antitrust and patent law. Although antitrust is not entirely centrally administered, the Commission takes on a leading role in creating antitrust policy. National competition authorities' influence on the creation of a common innovation policy might be limited, though this might vary from country to country.[35] In any case, patent law in Europe is institutionally fragmented (as discussed in chapter 9). In these circumstances, the Commission and the Court might find it suitable to use enforcement as a way of signalling to the patent authorities in the Member States and to the EPO that there might be an underlying problem.

24. It is not just the fact that the institutions operate at different levels and so communication resembling that between different DGs of the Commission is hard to conceive, it is also the fragmented nature of the patent system that might be justifying such steps. Even if one national system might be seen as dealing quite well with certain issues, this need not universally be the case. This can be illustrated by the differing approaches to the availability of patent injunctions as discussed in connection to SEP decisions. With legislative changes at the European level being hard to achieve, antitrust involvement might be the only available means to push individual patent authorities to change the way they work. Cases taken up by the Commission are often big money cases involving big market players and so they often receive considerable

[35] Cases subject to antitrust scrutiny at the national level might also vary in their nature in terms of the sectors considered. A scrutiny of merger decisions from the Polish NCA from the past five years shows that there has been not a single decision in which patent issues or indeed innovation issues have been raised. This can be explained by the nature of the notifications reaching that agency, which often concern sectors such as the energy sector, milk production or grocery stores, which are not typically innovative sectors. Whether the same conclusions could be reached in respect of antitrust decisions (or other NCAs) would require a further scrutiny.

media attention. Thus, through competition enforcement, the Commission can effectively draw attention to the underlying problem at hand. All of the case studies discussed in Part II could be taken as evidence of that trend. Each of them contained more or less direct criticism of the patent system which could be taken as an invitation to correct identified failures. The *AstraZeneca* decision expressly relied on the insufficiency of patent remedies to justify antitrust intervention. Notwithstanding the fact that the reasoning in SEP cases was less explicit in criticising the approach of the German patent courts to the issue of injunctions, it was meant to correct the imbalance created by the extreme pro-patent holder position taken by the national patent courts that invited a balancing exercise as part of patent proceedings.

25. Although, as a result, antitrust could be called a repair-it-all mechanism, the issues discussed in Part II show that it is not necessarily the best suited mechanism for solving the underlying issues. This is not just because it sometimes fails to provide an appropriate balancing of interests, but also because it provides rather crude remedies.[36] The alternative ways of approaching these problems through patent law might sometimes seem to be more natural solutions. Yet, antitrust authorities might be in a better position to oversee the difficulties with the functioning of the market as they arise through the use of particular patent strategies and to intervene in a more timely manner if there is such a need. Intervention in individual cases is effective in so far as it deters the parties from pursuing particular conduct, but also because it might spur regulatory action. We have seen that *AstraZeneca* brought about regulatory change, though not specifically in patent law per se, but rather in the process of obtaining marketing authorisations. Thus, the case could be taken to be an example of successful signalling. While the Court of Justice insists that a breach of other laws or regulations does not preclude antitrust liability because of the anticompetitive effects such conduct might have regardless of its status as a matter of other laws, such statements should be read as simply confirming formal competence and an assertion of the hierarchical position of competition law as against other legal provisions. If the signalling mechanism as elucidated here were to be successful, initial antitrust involvement should reduce the practical need for further such involvement in the future because it should bring about a reaction from the side of the patent system (be it in litigation,

[36] As recognised by the OECD (n 67), p 7: "competition law is a relatively blunt instrument for that purpose".

administrative practice, or legislative change) or other regulatory bodies that shape the competition conditions in a particular sector, thus providing an alternative solution to the problem. This should reduce the pressure on competition authorities to decide difficult issues concerning patent law and the innovative process surrounding it. The risk in applying such an approach is that the patent side will no longer see a need to solve the problem, since it will consider it already fixed by antitrust law (as can be exemplified by the repeal of section 44 of the UK Patent Act 1977 concerning patent misuse).

26. Although signalling through enforcement is an imperfect solution that can be seen as one born out of practical need resulting from separate treatment and relative institutional isolationism of antitrust and patent laws, in the European context there might be few other opportunities to achieve that aim. Admittedly, the sector inquiry context constitutes one such chance. In this sense, the pharmaceutical sector inquiry could be considered a lost opportunity, though the Commission used the occasion to make some recommendations for improvements in the patent system in the Report (and by the benchmark of other sector inquiries it already went quite far). This shows that there is a need for greater cooperation outside enforcement, a tool which is elaborated on below in section V, as a means of effectuating signalling between the agencies.

IV A scope for improvement within antitrust enforcement

Signalling back

27. The signalling interpretation of antitrust involvement in patent matters is, however, only the first half of the story. While it does not eliminate the need for antitrust involvement, but only diminishes it, for a real interaction to occur, patent law has to find a way to signal back. The aim of this signalling back is quite straightforward: it is to increase antitrust awareness of the impact it has on patent matters and thus guard against a pro-competition bias by increasing exposure. As things stand now, however, at least within enforcement, there is little possibility of securing such input other than through expert witness or other evidence submitted by the parties. While there exists a possibility of intervening in a case before the CJEU, to succeed with an application to

intervene one must establish an "interest in the result of a case"[37] and is "limited to supporting the submissions of one or other of the parties"[38]. The possibility to intervene is also limited to direct actions.[39] Intervention is thus very different from a possibility of submitting *amici curiae* briefs as practiced in the US courts. While allowing a brief remains within the discretion of the court, the purpose of an *amicus curiae* is to assist the court rather than to support one of the parties to the case.

28. Similarly, within the realm of administrative decision-making, there is little possibility of obtaining external input concerning patent issues that would not be submitted as evidence by the parties in support of their defence. Admittedly, draft decisions prepared by DG Comp are submitted to inter-service consultation before they are officially stamped by the Commissioners and become Commission decisions. Yet, supporting EU IPR policy is only one of the wide array of matters entrusted to the DG for the Internal Market, Industry, Entrepreneurship and SMEs. Although an IPR strategy is one of the components of the Innovation Union flagship initiative led by that Directorate General, it is not clear whether the inter-service consultation mechanism is sufficient to give the patent side of the matter a sufficient voice. Definitely though, it is a step towards ensuring signalling back. The above observations should in no way be taken as suggestions that competition law decision-makers are lacking in knowledge of patent law.[40] However, as it was already discussed, such knowledge might not be sufficient to avoid a pro-competition bias resulting from lack of exposure. It is only natural that officials repeatedly exposed to similar issues and put in charge of enforcing a particular field of law will develop a way of analysing issues that might undervalue certain external perspectives. Signalling back is aimed at countering this.

29. So, unlike signalling, signalling back might be an instrument which at best is currently underdeveloped. It should be noted, however, that the form of signalling back explored above is a bit different in nature from signalling discussed in the preceding section. The way it is expected to work within enforcement is by providing external

37 Art 40(2) of the Statute of the Court of Justice.

38 Notes for the Guidance of Counsel in written and oral proceedings before the Court of Justice of the European Communities (Feb 2009), p 18, see also arts 129 and 132 of the Rules of Procedure of the Court of Justice of 25 September 2012 (OJ L 265), as amended on 18 June 2013 (OJ L 173) and on 19 July 2016 (OJ L 217).

39 Guidance of Counsel (n 38), p 18. Title III of the Rules of Court concerning preliminary rulings does not contain provisions on intervention corresponding to those contained in Title IV concerning direct actions (Chapter 4).

40 Indeed, personal experience suggests otherwise.

input to antitrust decision-making process, rather than by using patent involvement in an innovation matter to suggest a shift in competition policy. This variation is justified not only by the fragmented nature of the patent system (suggesting that individual cases might have a more limited impact), but also by the practical dynamics in which issues arise. This approach accepts that in certain circumstances antitrust involvement in patent matters serves a useful purpose. The focus of signalling back is rather on the ways in which to improve the quality of antitrust decision-making.

30. The analysis of the decisions in Part II has shown that application of antitrust law to patent matters indeed might be in need of improvement. This is not only because it generally does not pay sufficient attention to the innovation angle of the matters put before it, but also because its treatment of the dynamics of competition within the patent realm might not be sufficiently in-depth. While antitrust decisions might be said to be favouring follow-on innovation, this rebalancing of interests is not a result of an open discussion of the trade-off made. Considering how great an impact antitrust decisions might have on the reward system built through patent law and policy, any recalibration of the trade-off deserves a proper examination in the decisions subject to enforcement. Taking into account the strong precedent value of individual decisions of the European Commission and the CJEU in a system in which public enforcement continues to play a leading role in shaping policy (thus limiting the number of cases that are subject to an authoritative ruling), the need for doing so becomes even more pressing. An enhanced level of analysis that takes into account the interests of breakthrough innovators and the dynamics of competition in innovation more generally would be a step towards countering possible pro-competition bias. Introduction of more balancing into the antitrust analysis does not need to mean that the outcomes of the Commission decisions would suddenly become drastically different, but only that they would be a result of a more balanced decision-making process that ensures that important interests affecting innovativeness are not ignored. A greater exposure to the other side of the innovation equation through signalling back could boost a change of mentality. A greater focus on the innovation dimension might, however, require working out new balancing tools to address the trade-offs at play. The flexibility of the legal instruments available to the Commission provides space for

such progression.[41] First, however, it is important to make sure that all the relevant elements are put on the scale before they are assigned a particular weight.

The limits of signalling as a justification for antitrust involvement - the need for an additional tool that would allow for an effective division of functions

31. The discussion of the need for signalling back as a means of countering pro-competition bias presupposes a continuing role for antitrust law in patent matters. While signalling back goes to the question of 'how' such involvement should look like, the 'if' question remains a relevant topic of discussion. Neither US or the EU courts provide a general overarching answer to the question of relationship between antitrust and patents that would collectively explain separate instances of antitrust involvement in patent matters.[42] The signalling justification for antitrust involvement accepts that antitrust might not be the most straightforward way of solving the underlying problem, but that nonetheless practical necessity demands antitrust intervention. This might be justified by the temporal aspect of antitrust intervention and the flexibility it offers. Yet, turning the question of antitrust involvement in patent matters upside down, are there any issues in which antitrust should not get involved despite the utilitarian justification based on practical need and signalling? As it was pointed out above, the tests utilised by the Court for deciding the issue of antitrust involvement share a common idea that there is a nucleus of patent policy in which antitrust should not get involved. After all, in some circumstances, the authorities seized of the patent matter might be much better suited to assess the trade-off to be made, to an extent that renders antitrust involvement counterproductive or even inappropriate, despite the utility of the signalling effect. While the tests devised by the Court do not offer an effective solution to that potential problem, there remains a scope for improvement in antitrust decision-making in that sphere as well. Various academics attempted to address this problem.

32. A controversial pre-screening test has been proposed by Carrier.[43] He proposed a test whereby a presumption against antitrust involvement should apply if "there is a

41 Despite the limits put on proving an innovation defence.

42 Thorsten Käseberg, Intellectual Property, *Antitrust and Cumulative Innovation in the EU and the US* (Hart Publishing 2012), p 24.

43 Michael Carrier, "Unraveling the Patent-Antitrust Paradox" (2002) 150(3) University of Pennsylvania Law Review 761.

plausible justification for the action other than injuring competitors." [44] This presumption is not intended to operate as a detailed balancing of pro- and anti-competitive effects.[45] It would be subject to a rebuttal if innovation in a market in which practice took place was competition rather than patent driven, from both *ex ante* and *ex post* perspective. In such case, section 2 of the Sherman Act would apply,[46] unless the defendant could show that the relevant market is in fact "marked by innovation" (surrebuttal).[47] While this test could be commended for trying to put innovation at its heart, it can be criticised at many levels. Firstly, it is not clear what sort of justifications for the patent based actions would be accepted to apply the presumption. All in all, nearly all patent based actions are meant to exclude and so 'harm' competitors. In *Lundbeck* the defendant unsuccessfully tried to use an alternative explanation of its actions as a defence. While the Court considered the existence of the alternative explanation for the conduct to be of no relevance, it could be taken to demonstrate that in theory it is possible to distinguish between different justifications for a patent based action in a way suggested by Carrier.

33. Secondly, the way the rebuttal is formulated, it becomes immediately clear that this test is meant to be industry specific. Industry specificity in competition assessment is an interesting idea, but to use it for a pre-screening test to decide whether antitrust involvement is warranted is another matter. In such scenario, it could be the market and not the nature of the practice which could become decisive for the question of antitrust involvement. This is particularly troublesome since the test is based on controversial preconceptions as to the nature of certain industries.[48] Effectively, industries are divided into categories, where some are almost conclusively believed to be competition driven and some patent driven – a distinction that finds no place in patent law[49] and that is hard to sustain also more generally. In any case, the test was

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44 ibid, p 817.

45 ibid, p 818.

46 The test was invented with the US jurisdiction in mind.

47 Carrier (n 43), p 833.

48 Carrier considers that the pharmaceutical and the ICT sectors lie at the opposite ends of a spectrum, where at one extreme innovation is patent driven (pharmaceutical industry) and at the other it is competition driven (ICT/software industries). Not everyone, however, agrees with that division – Tilford, for example, likens pharmaceutical and ICT sectors arguing that both of them have high R&D costs and hence face similar exposure to risk (Simon Tilford, "Is EU competition policy an obstacle to innovation and growth?" (2008) Centre for European Reform essays, p 3).

49 Although the question of optimisation of patent law by differentiation of patent protection according to the needs of particular industries is not unknown to IP law discussion, so far it has not found reflection in the law.

devised with monopolists in mind, so its application would be limited to situations potentially falling under article 102.

34. Other tests also suffer for being of limited application. For example, Kaplow's "ratio" test was invented specifically with licensing agreements in mind,[50] although one could try to apply it to other contexts. That test "examines the ratio between the reward the patentee receives when permitted to use a particular restrictive practice and the monopoly loss that results from such exploitation of the patent."[51] The higher the ratio, the less reason for intervention. This test, based on the economic trade-off between the reward system and the costs which that system entails,[52] is not a pre-screening test, but rather it combines the question whether antirust should get involved with the way in which it should get involved. In other words, it defines the circumstances when antitrust intervention is warranted and at the same time provides a mode for assessment of the practice at hand. Yet, the author of the test himself admits that it would be difficult to apply that test in practice. What it manages to achieve, however, is to involve two sides of the equation in the balance.
The same cannot be said of Baxter's "comparability" test or of Bowman's "competitive superiority" test.[53] Both of these tests also suffer from the difficulty of practical application.

35. A more interesting approach is proposed by Käseberg.[54] On the basis of "positive economic analysis" he attempts to find a middle ground between an a 'pure' IP solution whereby a solution to nearly all "competitive problems due to 'over-shooting' IP protection" would be to change the patent system and a system in which antitrust is used as a discretionary "fine-tuning device".[55] While either extreme presents some

50 Carrier (n 43), p 797.

51 Louis Kaplow, "The Patent-Antitrust Intersection: A Reappraisal" (1984) 97 Harvard Law Review 1813, 1813. See further Ian Ayers and Paul Klemperer, "Limiting Patentees' Market Power 'Without Reducing Innovation" (1999) 97(4) Michigan Law Review 985.

52 The test focuses on the "economic welfare loss" (Kaplow (n 51), p 1889), so on total welfare rather than consumer welfare. It could also be criticized for putting private returns and social cost (in form of static harm) on the same scale and for not directly concentrating on building a system of incentives.

53 Kaplow criticizes both (n 51). The "comparability" test provides that a patent holder should be allowed to restrict the use of their invention provided that the restriction is confined "as narrowly and as specifically as the technology of his situation and the practicalities of administration permit" (William Baxter, "Legal Restrictions on Exploitation of the Patent Monopoly: An Economic analysis" (1966) 76 Yale Law Journal 267). It thus emphasises antitrust solution to the innovation problem while playing down the patent side of the equation. The "competitive superiority" test does the opposite by saying that a patent holder should be allowed to use the restrictive practice for as long as it "measures the patented product's competitive superiority over substitutes" (Ward Simon Bowman, Jr, *Patent and Antitrust Law: a legal and Economic Appraisal* (University of Chicago Press 1973).

54 Käseberg (n 42).

55 ibid, pp 60-63.

problems, Käseberg proposes instead a comparative cost-benefit analysis depending on the competition problem. While this approach does not offer a quick fix solution for the filtering of cases either, but only some meta rules to follow, it is recommendable for it seeks to find a practical solution based on which body of law is perceived to be better suited to address a particular problem at the antitrust-patent interface. As such, this approach seeks to establish a more integrated thinking about the issues at the crossroads between the two fields. It thus distances itself from (over) emphasising of the functional division of tasks between the two fields of law, by which IP policy is confined to an 'innovation rationale' while antitrust should follow 'the competition rationale'.[56] It also presupposes a heightened degree of coordination between the institutions responsible for antitrust and patent policies. This practical economic approach could be linked to the signalling interpretation of antitrust intervention, which at the end of the day seeks to achieve the position whereby a field of law best suited for the task is left with the balancing exercise.

36. Admittedly, the signalling interpretation explored above is a strictly utilitarian approach to the interaction between antitrust and patent policies that accepts the practical reality in which patent policy is developed. However, in a perfect world, the justification for antitrust enforcement should be grounded more closely with the economic justification for the division of tasks. To achieve that, a cooperation (and so another form of signalling) outside enforcement would be a step towards working out which set of laws might be best suited to address any problems that might arise. With this consideration in mind, the next section considers the form such cooperation and communication could take.

V A need for greater cooperation outside enforcement

37. While signalling back has the potential to reduce the pro-competition bias as exhibited by the competition authorities, the signalling mechanism as conceived for enforcement does not act towards addressing the opposite pro-patent bias. It is also an imperfect solution that is an answer to the practical reality, rather than one based on strictly economic thinking about the division of regulatory competence. It does not answer the question whether there should be any 'no go' areas for antitrust law. Even if the need

[56] ibid, p 64; Cf Heike Schweitzer, "Controlling the Unilateral Exercise of Intellectual Property Rights" (2007) EUI Working Paper LAW 2007/31.

for antitrust intervention might reduce with time as alternative ways of dealing with a problem are created, an already established precedent opens the doors to private litigation. This problem, however, might be offset by the fact that in Europe damages are not meant to be punitive, so if an alternative remedy exists, recourse to competition law should not offer an advantage.[57] In any case, interaction of antitrust and patent authorities outside enforcement might be a more constructive way of addressing the problems at the antitrust-patent intersection. This way of communicating has the advantage of addressing both types of biases and for offering a possibility of an open discussion of the trade-offs to be made as well as regulatory choices that are most suitable for a given situation. Also, just like the use of signalling in the enforcement context, cooperation outside enforcement can also reduce the need for antitrust involvement just as much as it can improve the quality of the decision-making.

38. With DG Growth being responsible for the development of the EU patent and innovation policy, it could be argued that there is already (a potential for) an internal platform for discussion of the issues at the antitrust-patent intersection within the Commission. However, there is only a small team within Directorate for Innovation policy and Investment for Growth that deals with intellectual property.[58] Unlike in case of trademarks and designs, there is no separate EU agency specifically devoted to developing patent policy.[59] Moreover, since patent policy is not within the exclusive competence of the EU and remains un-harmonised, DG Growth is in no position to influence the existence of the pro-patent bias. The bodies that take a leading role in developing patent policy in Europe - the EPO and soon the UPC - are external to the EU legal system. It is them, together with the 28 national patent authorities, that should form the other side to the conversation. Yet, this fragmented nature of the patent system, with 28 separate national patent systems supplemented by the new unitary patent and the European patent, makes interaction more difficult. While it could be said that the same problem exists on the competition side, the success of the

57 Also, treble damages are not available in Europe, unlike in the US - this eliminates a potential reason for cutting back on antitrust enforcement in favour of patent solutions: Korah (n 15), p 170.

58 F5 within the new DG as restructured in the summer of 2015; organisation chart available at http://ec.europa.eu/DocsRoom/documents/20881 (accessed 20 January 2017).

59 European Union Intellectual Property Office (EUIPO, formerly OHIM) manages the EU trade mark and the registered Community design and also works with the Member States' intellectual property offices to coordinate the trademark and registered design experience across Europe. It is supervised by the DG Internal Market, Industry, Entrepreneurship and SMEs.

ECN and the dominant role that the EU competition law plays somehow alleviate that problem.

39. Thus, it could be said that there currently exists no established channel for communication between competition and patent authorities in Europe. The communication between the CJEU and the forthcoming UPC through the preliminary rulings procedure is discounted in the present context, since it concerns enforcement context and also it only operates top-down, rather than as communication that occurs both ways. The closest one could get to having a platform for cooperation is through one-off consultations. Sector inquiries conducted by the Commission could constitute a good opportunity for discussing problems in specific sectors. Indeed, in chapter 5 we have seen that the EPO was actively involved in the consultation process, with an EPO officer being actually seconded to the Commission for several months,[60] and that in its report the Commission decided to give recommendations for the improvement of the patent system that could also serve to improve the competitive environment. Already in that Report it was suggested that the EPO was in the process of introducing some changes, partially as a reaction to the signalling received from the Commission. Competition policy makers' interest in similar consultations happening on the other side, however, can be looked for in vain.

40. What of other external platforms for discussion? The OECD is a global platform that does some great work in promoting topics in the area of competition policy. It organises roundtables and publishes policy papers on various topics, which in the past included papers on competition policy and IPR,[61] patents and innovation,[62] intellectual property and standard setting,[63] effects of disruptive innovation on competition enforcement,[64] or competition in the pharmaceutical industry.[65] Apart from

60 Theon van Dijk, "On possible cooperation between patent offices, competition authorities and SSOs", OECD Competition Committee Hearing on Standards Setting Paris, 17 December 2014, available at http://www.slideshare.net/OECD-DAF/ip-standard-settingtheonvandijk17dec2014 (accessed 20 January 2017), slide 3.

61 OECD, "Competition Policy and Intellectual Property Rights" (1997) DAFFE/CLP(98)18, available at https://www.oecd.org/daf/competition/abuse/1920398.pdf (accessed 20 January 2017).

62 OECD, "Competition, Patents and Innovation" (2006) DAF/COMP(2007)40, available at https://www.oecd.org/competition/abuse/39888509.pdf (accessed 20 January 2017); OECD, "Competition, Patents and Innovation II" (2009) DAF/COMP(2009)22, available at https://www.oecd.org/daf/competition/45019987.pdf (accessed 20 January 2017).

63 https://www.oecd.org/daf/competition/competition-intellectual-property-standard-setting.htm (accessed 20 January 2017), recognising that "[c]o-operation between SSOs, patent offices and competition authorities can be useful" (Executive Summary p 4).

64 OECD, "Disruptive innovations and their effect on competition" (2015) available at https://www.oecd.org/daf/competition/disruptive-innovations-and-competition.htm, (accessed 20 January 2017); OECD, "The impact of disruptive innovations on competition law enforcement" (2015

establishing a platform for discussion on its own, some of the roundtables underlined the need for cooperation between the authorities. To take the example of the roundtable discussion on standards, one of the expert presentations given by the Chief Economist at the EPO explored the potential for cooperation between the SSOs, patent offices and competition authorities. He gave examples of how patent expertise can be used in competition cases and in the consultations concerning new competition regulations, such as the new TTBER.[66] In a similar vein, the 2004 Roundtable on IPR recognised that competition authorities should "try to improve IP agencies' awareness of competition issues so that the latter agencies can begin to take any necessary steps to improve the IP approval process themselves."[67] In this way antitrust can provide competition input also in areas of patent policy in which it does not get directly involved in its enforcement, such as availability of divisional applications. [68] The Commission sometimes, but not always, also provides contributions to the roundtables organised by the OECD.

41. One of the ways in which cooperation is encouraged is by providing guidelines on the competition enforcement in the area of IPR.[69] Such guidelines are not only useful for patent holders and patentees, but also their preparation could provide a good setting for establishing cooperation between authorities. The Commission has not, however, issued patent- or IPR- specific guidelines, with the exception of guidelines on transfer agreements.[70] In this respect, the level of activity of the US DoJ and the FTC remains unmatched. The DoJ and the FTC prepared not only guidelines on the licensing agreements for intellectual property,[71] but also worked together to issue several reports

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Global Forum on Competition) available at https://www.oecd.org/competition/globalforum/disruptive-innovations-competition-law-enforcement.htm (accessed 20 January 2017).

65 OECD,"Competition and Regulation Issues in the Pharmaceutical Industry" (2000) DAFFE/CLP(2000)29, available at https://www.oecd.org/daf/competition/sectors/1920540.pdf (accessed 20 January 2017); OECD Discussion on Competition and Generic Pharmaceuticals (2014) DAF/COMP/M(2014)2/ANN6/FINAL, available at http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=DAF/COMP/M(2014)2/ANN6/FINAL&doclanguage=en (accessed 20 January 2017) .

66 van Dijk (n 60).

67 OECD, "Intellectual Property Rights" (2004) DAF/COMP(2004)24, available at https://www.oecd.org/daf/competition/34306055.pdf (accessed 20 January 2017), p 7.

68 Cf the Italian *Pfizer* case discussed in ch 4, paras 47-54.

69 OECD, "Intellectual Property Rights" (2004) DAF/COMP(2004)24, available at https://www.oecd.org/daf/competition/34306055.pdf (accessed 20 January 2017), p 7; Carrier (n 43), 845-846: "Guidelines take a comprehensive approach to a particular area of law, contain supporting theory, and are not bound by the facts of any particular case."

70 OJ 2014 C89/3, and the previous version: OJ 2004 C101/2.

71 Originally issued in 1995, but recently revised: Antitrust Guidelines for the Licensing of Intellectual Property, Issued by the U.S. Department of Justice and the Federal Trade Commission (January 12, 2017).

and studies on the interaction between competition law and IPR, which considered the balancing of the roles between these two fields of law as well as contained an analysis of specific conduct.

42. There are two DoJ/FTC reports that deserve particular attention. First, in 2003 came the FTC Report on finding a proper balance between competition and patent law and policy which took an innovation perspective to the problem.[72] The purpose of this report was to give recommendations for the patent system to maintain a proper balance with competition law and policy. Then came the joint report of the DoJ and the FTC[73] which had an opposite purpose, which was to make recommendations for the competition authorities to maintain a proper balance with patent policy.[74] It concentrated on several specific issues, such as use of patents in standard setting context or application of antitrust to licensing agreements, but has not attempted to provide an overarching standard for justifying intervention and its limits though.[75] However, the preparation of the report provided a forum for discussion and for increasing awareness of the opposite perspective, which could be taken as a good way to counter potential biases the officials might have entertained.[76] Both reports were very widely consulted and provided an opportunity to hear many voices on the IPR side, which included associations, practitioners and academics alike.[77] This is not to suggest that the US example as presented above is an illustration of perfect cooperation. It is still one that is dominated by one side of the equation, with the US Patent and Trademark Office (USPTO) playing a secondary role in creation of innovation policy at the intersection between antitrust and patent law without a truly interdisciplinary approach being achieved. Yet, at least some form of a more in-depth cooperation has been attempted there.

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72 FTC, "To Promote Innovation: the Proper Balance of Competition and Patent Law and Policy" (October 2003).

73 US Department of Justice and the Federal Trade Commission, "Antitrust Enforcement and Intellectual Property Rights: Promoting Innovation and Competition" (2007).

74 FTC Report (n 74), p 1.

75 The recently revised joint FTC and DoJ Antitrust Guidelines for Licensing of Intellectual Property of 12 January 2017 (n 71) clarify, however, that IPRs are to be analysed like any other piece of property, taking into account their special characteristics (p 2)

76 As evidenced by the list of topics discussed during the hearings, which included topics that seemed to be intended as a learning opportunity, for example "antitrust law for patent lawyers" and "patent law for antitrust lawyers" (Appendix D to the Report, p 167).

77 See Annexes A, B and C to the 2007 Report (n 73), the Agencies heard from over 300 panelists and received over a 100 written submissions (p 3); the Hearings were held jointly for both Reports.

43. In her speech on enforcement priorities Commissioner Vestager stated that issuing of guidelines is easier once there is some enforcement practice to rely on.[78] Whatever IPR guidance is provided in the general guidelines on the application of article 101 and guidance on the application of article 102, it is usually limited to issues that have already been considered by the CJEU. The Commission has been very careful not to say too much in those soft law instruments. However, providing further guidance could turn out to be of benefit for the Commission itself. The precedents that are already there can provide a basis for a more abstract discussion of the balance to be achieved between competition and patent policy demands. Patent authorities should be engaged in any such discussion to expose the Commission to the opposite perspective on the dynamics of the innovation process. In this way, the Commission could guard against the risk of a pro-competition bias, which could hopefully lead to more balanced enforcement that is sensitive to the dynamics of the innovation process in the patent context.

44. Development of any form of cooperation between the agencies, be it *ad hoc* or more regular (see section VI below), however, relies not only on the will of the relevant parties, but also (and perhaps mostly) on available resources. The issue of limited resources might be of particular importance to the EPO which has to deal with a growing number of applications and filings,[79] which might have the result of turning resources away from policy making. In general, administrative policy making on the patent side might be not as expansive or institutionalised as it is in case of competition authorities. At the same time, it is important for both sides that policy making teams manage to transpose the knowledge they gain into enforcement context as executed by the case handlers. To that effect, other forms of increasing exposure might become of relevance, such us training or secondments. The achievement of a truly innovation centred system might thus require some more drastic changes.

VI Towards an innovation centred system

45. When considering the regulatory choices made by the competition authorities in the patent context and the way they might affect the balancing exercise, one cannot forget

78 Vestager (n 32).

79 See the EPO's annual reports, available at http://www.epo.org/about-us/annual-reports-statistics/annual-report.html (accessed 21 January 2017).

the institutional set-up in which those authorities operate. Administrative agencies are limited not only by the substantive law which they are expected to apply, but also by the way the legal system is built. The multilayered and fragmented nature of the European legal system creates difficulties in ensuring interaction between the agencies and their officials. With full harmonisation not being a practical possibility, at least in the near future, the authorities need to adapt to the existing conditions. The conditions created through institutional design, in turn, might shape the way they work and the way in which the perceive problems. In the current institutional design antitrust law and patent law have been developing in isolation rather than as part of a common innovation policy. This is because the EU institutional design makes it difficult to establish cooperation between various policy making bodies operating at different levels. In the current framework it is easier for the Commission to establish links with other competition authorities and to conduct an intradisciplinary dialogue,[80] than to create interdisciplinary exchange to solve a common problem.

46. No one expects antitrust and patent law to be administered in the way antitrust and consumer law sometimes are, with the same authority being put in charge of both fields of law, like for example the Dutch ACM (Authority for Consumers and Markets), Polish UOKiK (Office of Competition and Consumer Protection) or the CMA (Competition and Markets Authority) in the United Kingdom.[81] There is an obvious difference between the two situations, and it is not necessarily lack of common objectives.[82] Rather, it is that both competition and consumer agencies are set up with the aim of overseeing the market,[83] while this is not the case with patent offices. In our minds competition and patent law are two fields of law that are almost completely separate in their functions. Indeed, if one looks at their daily operation, they do not have much in common. Yet, the functional overlap between competition and consumer law is not that much more marked to justify the difference in treatment.

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80 Not just through the ECN, but also through international networks such as the ICN, or by establishing *ad hoc* cooperation with other competition authorities in respect of individual cases. By design, DG Comp has a policy team devoted to international relations (A5) working on intradisciplinary dialogue.

81 The CMA replaced the OFT (Office of Fair Trading) and the Competition Commission in 2014.

82 Though, as it was explained in ch 2, the objectives pursued by antitrust and patent law are not necessarily the same. This difference makes it possible to argue that these two fields of law should never be jointly administered.

83 See Annetje Ottow, *Market and Competition Authorities: Good Agency Principles* (OUP 2015), p 21 for various reasons for 'agentification' (a mode of governance by which tasks are performed by semi-autonomous organisations at arm's length from the government).

Indeed, the potential for conflict between competition law and consumer law might be considered lesser than in the case of antitrust and patent law. Moreover, the pursuance of a common goal of consumer welfare by competition and consumer authorities does not necessarily suggest substantive functional overlap. Yet, the limited functional overlap that exists between competition and consumer law could be said to justify joint administration. Among the reasons given for choosing an "integrated model" as opposed to a "coordination model"[84] there is the a need to achieve a more balanced integrated approach and to make it easier to use other authority's knowledge.[85] These are exactly the goals that should be pursued in respect of antitrust and patent policies to avoid (or to limit) the risk of pro-competition and pro-patent biases that might be harmful to innovation.

47. Yet, the above should not suggest that that the management of the intersection between antitrust and patent policies is in a lost position due to the fact that an integrated approach is not a practical possibility. Firstly, the success of an integrated approach is not a given and depends on a number of factors.[86] A multifunctional agency might still be functioning on a separate fields basis if its internal design does not promote cooperation. Secondly, there could also be downsides to an integrated approach, loss of focus being chief among them. A problem solving approach[87] allowed by the integrated model of interaction might also be achieved through advanced coordination. Co-operation outside enforcement might secure a sufficient input in terms of opening access to the knowledge of the other agency. Also, it might be a successful mechanism for signalling that a problem might be better solved at the opposite end. Yet, for this to succeed a more regular, perhaps formalised, form of co-operation going beyond the modes suggested above in section V might be preferable. Still, even with more regular co-operation between the agencies, it might be more difficult to achieve a problem-solving approach through coordination model than through a fully integrated approach. An integrated approach might have an advantage of offering flexibility to decide immediately which field of law is better suited for a problem at hand and assign the case accordingly. In a coordinated approach this

84 Annetje Ottow, "The Institutional design of competition agencies - A Dutch case study" (2014) 2(1) Journal of Antitrust Enforcement 25, p 29.

85 ibid, p 34.

86 Ottow (n 84).

87 See Malcolm K Sparrow, The Regulatory Craft (Brookings Institution Press 2000); Donald Chisholm, "Problem-Solving and Institutional Design" (1995) 5(4) Journal of Public Administration Research & Theory: J Part 451.

outcome might be achievable only in the long term, after initial enforcement undertaken by one side (most likely the competition authorities). Thus, if one wants a truly innovation centred system, then perhaps a major institutional re-design would be necessary. Nevertheless, looking at the types of solutions that the patent system could offer to the competition problems raised in Part II, it immediately becomes apparent that they are long term solutions. Thus, it would seem that the flexibility of problem assignment offered by the integrated model does not offer an advantage to the management of the antitrust-patent intersection problem.

48. This leaves us with the coordination model as the preferred mode of interaction between antitrust and patent policies in the European legal system. This coordination would need to take a more heightened form than at present if an innovation centred system were to be the aim. In this respect, *ad hoc* projects such as sector inquiries conducted by the Commission should be taken only as a limited first step towards a problem solving approach. All in all, the pharmaceutical sector inquiry was only meant to be a market investigation and so a pre-step before any suggestions to the problems identified therein could be offered. It highlighted the dominant role of the competition law side in managing the innovation puzzle in the patent context. A problem solving approach that such an inquiry could initiate would require in-depth engagement of both types of regulatory bodies, not simply through consultations regarding the text of the Report.

49. When it comes to providing access to expertise knowledge, on the other hand, heightened coordination might include having experts in competition and patent policy within respective agencies. Although at first sight this step might seem to be going beyond and above what is required, it is not an unthinkable solution. In fact, at least for a while the FTC had a special counsel for intellectual property within its Bureau of Competition and a Project Director for Intellectual Property within the Office of the General Counsel.[88] If DG Comp wishes to remain active in the field of intellectual property, and the importance of the potentially affected industries suggests that it will, having such experts would heighten the credibility of its decisions. Such step could be likened to the decision to start employing economists within DG Comp when its enforcement has moved towards more economic thinking. Equally, having competition experts involved in patent policy creation on a permanent basis could

[88] See 2003 FTC Report (n 72), list of Report contributors on the cover matter.

direct patent systems, as they evolve through the EPO and national patent offices, closer towards an innovation perspective.

VII Wider perspectives

50. Examination of the patent-antitrust intersection and its comparison to the interaction between competition law and consumer law begs a question whether this problem is unique or whether there are lessons to be learnt here from other regulatory intersections. Inversely, could the signalling mechanism as elaborated on above be used in other regulatory contexts? All in all, examining regulatory regimes from a competition perspective is not a novel idea for a competition agency.[89] Although such examination usually concerns regulatory regimes applicable to a particular industry,[90] there is nothing that could prevent the Commission from providing an input on the competitive impact of other laws, such as certain aspects of contract law. Yet, it is an everlasting feature not only of legal scholarship,[91] but also practice that issues are analysed in a segmented manner through the application of one field of law without considering the overall picture or other sub-fields of law.

51. It might be said that this problem of isolationism of different fields of law is intensified in the European context in which it is not just a question of lack of communication between different branches of government or governmental agencies. It might be an unintended consequence of the division of competences between different levels that makes governance at the borders more challenging. To make a comparison, in the US establishing an effective interaction between the FTC and the USPTO might be easier as they are both federal agencies. In Europe, on the other hand, it is not just a question of managing the EU and the national level, but there is also an external element in the form of the EPO. The way in which antitrust-patent interdependency develops in the European context might thus also be seen as a problem of regulatory design.

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89 William Kovacic and Andreas Reindl, "An Interdisciplinary Approach to Improving Competition Policy and Intellectual Property Policy" (2004-2005) 28 Fordham International Law Journal 1062, 1085.

90 Indeed, on a national level in particular, the interaction between competition agencies and bodies responsible for the regulated sectors is often a very active one, and sometimes also takes an integrated form; see Ottow (n 84), p 29 table 1.

91 Jan Smits and William Bull, "The Europeanization of Patent Law: Towards a Competitive Model", in Ansgar Ohly and Justine Pila (eds) *The Europeanization of Intellectual Property Law: Towards a European Legal Methodology* (OUP 2013), p 39.

52. Yet, even if this makes the situation somehow unique there are still some meta rules that might be applicable to other contexts. For one, it is important to remember that a proper policy analysis takes a whole set of institutions, agencies and actors into account in making an assessment of a given situation.[92] A policy pursued by one body, such as patent institutions, might have unintended consequences in terms of how it is used by private actors or in the way it impacts other policies. Yet, the situation might be subject to correction by either private or public actors. Thus, to look at either antirust institutions or patent institutions in isolation when assessing the innovation policy in the patent context might be a mistake. It is in the recognition of the interdependency of the two fields that the key to creating a successful innovation policy lies. Moreover, depending on the context, other regulatory bodies might also have a role to play and indeed be a key to a problem arising at the antitrust-patent intersection. For example, the discussion of injunctions in the standard setting context (chapter 6) showed that increased involvement of the SSOs might be indispensable to solving the issue. Equally, in regulated industries, such as the pharmaceutical industry, the role of the bodies issuing marketing authorisations or setting reimbursement rates should not be underestimated.[93]

VIII Conclusions

53. When looking at the antitrust-patent intersection from the innovation perspective, it becomes clear that steps need to be taken to strengthen the decision-making process so as to manage the biases that both competition and patent authorities might display. While these biases are seen to be partially stemming from separate treatment of antitrust and patent law, steps both within and outside enforcement are suggested to counter those in order to achieve more balanced results. Separate treatment should be criticised for confining antitrust and patent law to a limited understanding of their functions, based on 'competition rationale' and 'innovation rationale' respectively. In

92 Michael L Katz, "Intellectual Property Rights and Antitrust Policy: Four Principles for a Complex World" (2002) 1 Journal on Telecommunications and High Technology Law 325, p 327; see also William Kovacic, "Competition Policy and Intellectual Property: Redefining the Role of Competition Agencies", in François Levêque and Howard Shelanski (eds), *Antitrust, Patents and Copyright: EU and US Perspectives* (Edward Edgar 2005), pp 3-4.

93 As recently recognised by Commissioner Vestager in a speech concerning the pharmaceutical sector, using competition rules need not always be the best solution: Margrethe Vestager, "Restoring Trust in our economy", Speech of 27 January 2017 available at https://ec.europa.eu/commission/2014-2019/vestager/announcements/restoring-trust-our-economy_en (accessed 28 January 2017).

this way, the interdependency of the fields of law becomes undervalued. The problems that this might create were reflected in the reasoning of antitrust decisions as analysed in Part II.

54. Separate treatment cannot ignore that patent concepts are being increasingly "interpreted and applied in light of other interests".[94] The impact of competition law might be to "shape some of the core issues"[95] of patent law. The question is whether this is done through appropriate balancing. Equally, while patents are granted without regard to how they will be used, for as long as an invention meets the patentability criteria, it does not mean that patent policy should not take account of the economic effects of patenting and that the patent litigation system should not respond to usage of patent rights which is not in line with patent policy.[96] This interdependency of antitrust and patent policies is, however, too often neglected, meaning that that they might be pulling in the opposite directions without due regard for the impact they have on each other.[97]

55. Yet, despite this apparent isolationism, Commission decisions might be read as a signal to the fragmented European patent authorities that changes might be required or that new mechanisms need to be established within the system of patent litigation. This signalling mechanism might be taken as an imperfect utilitarian tool born out of practical need and the relatively convenient position of the Commission acting as a competition authority which allows it to monitor the functioning of the market and react relatively speedily through enforcement when the situation so requires. If successful, it should eventually ease the pressure put on the competition authorities to assess cases raising patent issues. Yet, while this mechanism will not eliminate the need for antitrust enforcement, especially in respect of novel issues, an improvement within antitrust enforcement is required to guard against the risk of the pro-competition bias. To achieve that establishing a mode for signalling back from the patent side might be a useful development. At present, the possibilities of obtaining an

94 Alain Strowel and Hee-Eun Kim, "The Balancing Impact of General EU Law on European Intellectual Property Jurisprudence", in Ansgar Ohly and Justine Pila (eds) *The Europeanization of Intellectual Property Law: Towards a European Legal Methodology* (OUP 2013), p 142.

95 ibid.

96 Cf Juha Vesala, "Misuse of Patent Application Procedures: A Case for Condemning Non-misleading Strategies?", in Rosa Maria Ballardini, Marcus Norrgard, and Niklas Bruun (eds), *Transitions in European Patent Law: Influences of the Unitary Patent Package* (Wolters Kluwer 2015), p 271.

97 Kovacic and Reindl (n 89), p 1082: "Recognition of the interdependency can provide the foundation for specific measures to reduce friction between the two systems and promote the achievement of shared policy aims."

external output that would not be submitted in defence of the parties as evidence are limited.

56. Establishing cooperation outside enforcement would also be recommendable as a means of establishing effective interaction and thus a further mode of signalling. In fact, this means of communicating should take precedence over imperfect signalling through enforcement. Establishing an interdisciplinary dialogue, however, might be challenging in a fragmented system operating on many levels and through a variety of actors. The use of external platforms, such as the OECD, might be useful, but not necessarily sufficient. Other, more formalised, forms of coordination should be tested as well. To that effect, having patent experts within DG Comp and competition experts within patent system could be an interesting development. The fragmented nature of the patent system means that the institutional dynamics in Europe evolve differently than in the US. It also means that an integrated model of cooperation is not a practical possibility. This should not, however, suggest that cooperation between the agencies needs to be necessarily suboptimal. The goals that an integrated model seeks to achieve can also be achieved through a coordination model. The important thing, however, is that communication should occur in both directions to counter both types of biases that might occur.

57. Signalling raises, but does not solve, the issue of assigning of problems between antitrust and the patent side. While antitrust overview can be used as a second filter to fish out situations which were not predicted at the time patent policy was created (since private actors will always use patent mechanisms in creative ways, not always in line with the policy underlining those rights), it provides rather crude remedies. To that effect, cooperation between the agencies might also serve the goal of more effective division of tasks. In this way the balancing exercise implicit in analysing the issues at stake might be delegated to the authority which is best suited for that task. The risk of biases in the decision-making process can be hence again limited. The balancing exercise encompassed in the reasoning process underlying a decision should thus include also balancing of the roles each authority should play. If signalling through antitrust enforcement is not picked up, the use of antitrust to fine-tune the patent system might become problematic.[98] At the same time, shifting all the

[98] Michael L Katz, "Intellectual Property Rights and Antitrust Policy: Four Principles for aComplex World" (2002) 1 Journal on Telecommunications and High Technology Law 325, 352: "Absent

balancing to the realm of patent law will not always bring about a desired effect. Sometimes competition law might offer an advantage in providing a more specialised and differentiated system of rules.[99] At times the solution will not lie with a re-balancing of the patent granting system, but rather with adopting a mechanism to be used in patent litigation. This might be patent specific, or not. Other regulatory rules might also come into play, especially in regulated industries, such as the pharmaceutical industry. An innovation friendly regulatory environment requires looking at the whole picture beyond the barriers of a single discipline, rather than using one field as a Maslow's hammer.

legislation, using antitrust to fine tune intellectual property laws would very likely create more problems than it would solve"

99 Käseberg (n 42), p 61.

Chapter 11

Conclusion

1. This thesis addressed a topical issue of management of the antitrust-patent intersection, looking at the problem from an innovation perspective. It contributes to the field, first, by showing that from the innovation perspective the problem of biases present in both antitrust and patent decision-making might be a matter of concern in managing the antitrust-patent intersection. This conclusion is based on insight gained from the analysis of novel issues recently considered by antitrust authorities on one hand, and the analysis of the design of the forthcoming Unitary Patent Court on the other hand. Second, this thesis offers an examination of a signalling mechanism as a way of addressing the problem of biases. The idea for a signalling interpretation explored in this thesis arises out of the analysis of the case studies themselves, which suggested that antitrust involvement in patent issues might have been triggered by the perception of failure or the inability of the patent system to address the issue by itself. While observing that antitrust cases picked up by the Commission might serve as a signalling device for the patent system intended to prompt development of an alternative solution to the problem at hand, ways of developing further a communication by signalling were explored in an attempt to combat the risk of biases and as a means of achieving an effective division of tasks.
2. By adapting a signalling approach this thesis advocates an interdisciplinary approach to antitrust-patent intersection. It argues that a separate treatment of these disciplines, advocated by some commentators, contributes to the problem of biases, potentially to the detriment of innovation. This research was based on a premise that both patent law and antitrust have a role to play in incentivising innovation and competition. This multidimensional understanding of the roles of each set of laws is compounded with a grounding assumption that both the state of competition and patent exclusivity have a role to play in incentivising innovation.
3. A further characteristic feature of this contribution is that it sought to combine the economic and a regulatory aspect of the treatment of the antitrust-patent intersection, thus giving it an EU-specific angle. It went to suggest that the management of the antitrust-patent intersection might be an issue that should be considered taking into account not just the legal provisions and their general economic underpinnings, but

also the full institutional set-up in place in a particular legal order, which is a standpoint that has not been previously explored in the literature concerning patent-antitrust intersection. The signalling justification for antitrust involvement in patent matters is based on the perception of the inadequacies of the alternative solutions as offered by the patent system, making an antitrust response grounded in the underlying regulatory system.

4. The analysis of the case studies performed in Part II of this thesis served to identify problems in the application of antitrust to patent related matters, looking at the issues raised therein from the innovation perspective. Consideration of different issues arising at the antitrust-patent intersection side-by-side allowed for discovering of some common trends and thus added to the knowledge about them. The analysis confirmed the suggestion made at the outset that competition authorities might be at risk of displaying a pro-competition bias in their decision-making by undermining arguments grounded in patent policy. The analysis did not try to establish what would be the optimal antitrust solution to a given problem, but rather what considerations should go into the reasoning exercise to ensure balanced results. Existence of a pro-competition bias might be harmful from the innovation perspective which requires balancing of the interests of competition against the rewarding role played by patent exclusivity. Competition authorities, however, struggle in balancing the often diverging interests at stake, or indeed with incorporating the innovation angle in the reasoning of their decisions. A comparison with the US treatment of the same issues supported a view held by Kovacic and Reidl that "[r]esolution of IP cases under EC competition law... tends to get less involved in [competition policy] and IP Policy aspects than is the case in comparable US cases".[1]

5. The case studies suggested that there is room for improvement in the Commission's and the CJEU's analysis. The scrutiny has also shown that there might be alternative solutions to the problems addressed by the antitrust authorities, suggesting that perhaps antitrust involvement is not always the best way to proceed. Since antitrust can provide only crude remedies to the patent problems it faces that might not evenly balance the need to provide both a "carrot and a stick" to incentivise innovative activity, the pro-interventionist stance of antitrust authorities is relevant also from the

[1] William E Kovacic and Andreas P Reindl, "An Interdisciplinary Approach to Improving Competition Policy and Intellectual Property Policy" (2004-2005) 28 Fordham International Law Journal 1062, pp 1076-1077; a tendency which they associate with the fragmented nature of the patent system, in which definition of patent rights remains a matter of Member State competence.

innovation perspective. By adapting a problem solving approach that centres around the need to promote innovativeness, novel patent issues recently considered by the European antitrust authorities have been put in a new light through the analysis performed in this thesis.

6. While the existence of a potential for pro-competition bias on the part of antitrust authorities has been explored through the analysis of Commission enforcement decisions, court rulings, and of a sector inquiry report, the risk of an opposite pro-patent bias has been shown through an analysis of the design of patent institutions, in particular the forthcoming Unitary Patent Court. This change of approach in demonstrating the existence of a risk of bias was justified by the changing institutional patent environment as triggered by the impending introduction of the Unitary Patent Protection. The consequence of the existence of each kind of bias might be that each field of law might be pulling in the opposite direction, rather than striving to achieve a balance which an innovation policy demands. Thus, the main research question stemming from that initial analysis that this thesis tried to answer was how to address the problem of those biases in order to improve the balancing of interests at stake.
7. To that effect, it has been argued that separate treatment of antitrust and patent policies contributes to the problem by confining each field to limited conflicting roles. The relative isolationism visible in the EU regulatory set-up was seen as adding to the problem of potential biases. The thesis thus explored the possibility of antitrust acting as a signalling device for the patent system and vice-versa. Under this interpretation, antitrust intervention did not just act as a "repair-it-all" mechanism, but also as a signalling device intended to trigger a reaction on the patent side. If picked up, such reaction could in turn alleviate the pressure and need for continued antitrust enforcement. While it could not completely eliminate the need for antitrust enforcement, in particular in respect of novel issues that may arise in the future, the thesis acknowledged the enduring need for improvement of the quality of antitrust analysis to provide a proper balancing of interests at stake, in particular those of breakthrough and follow-on innovators. To that end, the means through which signalling back could be ensured were explored.
8. While it was seen that the signalling device is an imperfect tool born out of practical need and that signalling back cannot act to eliminate the risk of a pro-patent bias, other means of coordination between antitrust and patent authorities were considered outside the realm of enforcement. While the fragmented nature of the patent system

was seen as a challenge in establishing an effective coordination going beyond *ad hoc* projects, still it was considered that establishing an interdisciplinary dialogue was essential to ensure exposure to arguments on the other side of the "innovation equilibrium". Such exposure should work towards combating possible biases on both sides and also could aid an effective division of tasks between different regulatory bodies.

9. The signalling interpretation of antitrust involvement in patent matters raised the issue of assigning of tasks between the antitrust and the patent side. It served as a justification for antitrust enforcement. While signalling back was used as a means of increasing exposure to the pro-patent arguments and so for the improvement of the quality of reasoning underlining the decisions, when used in the enforcement context it was not intended as a means of telling the Commission that it should not get involved in certain matters. However, the question of effective division of tasks (and so the question whether antitrust involvement is warranted) actually comes prior to the question how it should look like. The tests currently used by the Commission and the Court, as discussed throughout this thesis, cannot provide an effective means for deciding whether antitrust is an appropriate tool for dealing with a particular problem. They all hinge on arbitrary distinctions that do not lend themselves to predicting what sort of issues could come under the antitrust radar in the future. What they have in common though is an idea that there are certain issues at the core of patent policy in which antitrust law should not get involved. The signalling interpretation does not provide a direct answer to which issues could be outside the reach of antitrust enforcement in terms of formal competence, but since it is based on the practical need, it suggests that the answer should lie with competition priorities, the limits of competition tools in analysing patent issues, and the corresponding ability of the patent system to deal with the issue at hand. To this end, it is important to remember that the patent system is composed of both patent authorities responsible for managing the pre-granting stage and the patent litigation system in the post-grant stage that relies also on general private law. In the regulated industries, such as the pharmaceutical one, other regulatory bodies might also become relevant. Under a problem-solving approach, the question whether antitrust involvement is warranted should depend on the ability of other bodies to deal with the issue.

10. The analysis performed in this thesis also exposed some areas worth further exploration. Chief among them is the question of transferability of the findings to the

wider intellectual property context. The regulatory framework underlying other forms of IPRs is very different, so they might warrant separate examination. Furthermore, there is also the question of managing the tension between public and private divide in antitrust enforcement that went underexplored here, but which might have an effect on the Commission's reasoning and the approach to the antitrust-patent intersection more generally. Moreover, the practical ways in which cooperation between patent and competition authorities could be executed in the European context on a more regular, perhaps formal, basis would require further research. While the patent system in the EU is currently undergoing significant transformations, it might be prudent to see first how the new system is likely to work in practice. Once the UPC is established and builds a body of case law, its work could also be analysed in an attempt to establish whether fears of a pro-patent bias suggested by its design are reflected in its decisions.

11. The issue of the management of the antitrust-patent intersection is deemed to continue to be a topic warranting discussion, not least because of the new strategies devised by the patent holders to protect their interests that will inevitably come up in the future. The issue is without doubt one of huge economic importance. Effective balancing of the requirements of patent and antitrust policies is crucial to maintain the incentives to innovate. Promoting innovation is a central task for the future of R&D industries in Europe and antitrust and patent policies both have role to play in that task. This thesis is meant as a contribution into this discussion. It could also be seen as illustrative for the questions of management of other frontiers between various fields of law that might be seen as conflicting or in tension, especially if they are administered at different levels within the EU legal order.

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