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Vexatious (Patent) Litigation & Art. 82 EC Following *AstraZeneca* – EC and US Converging Approaches?

Abstract:

'Vexatious litigation' – a malicious legal action without probable cause, in which a litigant is not acting in good faith, but for the purpose of harassing an opponent or competitor – used as an anticompetitive weapon in patent enforcement proceedings is becoming a matter of increasing antitrust concern on both sides of the Atlantic. As any attempt to curtail the right to engage in such legal action is bound to involve not only the fundamental right of access to the courts, but also difficult issues at the direct point of intersection between IP and antitrust law, utmost care must be taken so as not to harm any of the competing interests. This thesis suggests that, in carrying out that balancing task, the approaches of EC and US competition authorities appear to be converging. In particular, the recent *AstraZeneca* decision provided by the European Commission constitutes proof of this.

Master thesis

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Summary

For many years, antitrust and intellectual property (IP) law were generally seen as being in conflict. The prevailing view was that intellectual property rights (IPRs) created monopolies to encourage innovation, while antitrust laws sought to eliminate monopolies.

Nowadays, antitrust and IP laws are more often viewed as complementary. According to this perspective, both areas of law seek – and work in unison – to maximise wealth by promoting innovation, economic progress and consumer welfare. But, even if there is agreement on the common goals, there is far less agreement on the appropriate balance between the regimes in particular situations.¹ For even though antitrust and IP law do not have conflicting aims, they strive to achieve them by different and sometimes conflicting means. Under some circumstances, tensions between the two branches of law are thus bound to occur.² Consequently, issues at the intersection of antitrust and IP law continue to attract much attention in the US as well as in the EC, not only within courts and competition agencies, but also within the policy community at large.³

¹ David A. Balto and Andrew M. Wolman, 867 PLI/Pat 9, June 2006, *Intellectual Property and Antitrust: General Principles*, p. 13.

² Katarzyna A. Czapracka, *Where Antitrust Ends and IP Begins – On the Roots of the Transatlantic Clashes*, I.J.C.L.P., May 2006, p. 24. See also Richard Eccles and Romain Ferla, *The Antitrust and IP Interface in the US and EU*, available at http://www.twobirds.com/english/publications/articles/The_Antitrust_and_IP_Interface_in_the_US_and_EU.cfm. Visited on June 20, 2007.

³ See presentations at the *US FTC/DOJ Hearings on Competition and Intellectual Property Law and Policy in the Knowledge-Based Economy* (February 2002), available at <http://www.ftc.gov/opp/intellect>. Visited on June 20, 2007.

See also speech by Timothy Muris *Looking Forward: the FTC and the Future Development of US Competition Policy*, December 2002, available at <http://www.ftc.gov/speeches/muris/handler.htm>. See further the FTC Report *To Promote Innovation: The Proper Balance of Competition and Patent Policy*, Oct 2003, (in particular Chapters 1, 2 and 5) available at <http://www.ftc.gov/opa/2003/10/cpreport.htm>; the *Patent Hearings in 2005* at <http://www.ftc.gov/opa/2005/06/patentconference.shtm> and <http://www.ftc.gov/speeches/majoras/050609compolicy.pdf> as well as most recently, FTC's *Testimony*, available at <http://www.ftc.gov/opa/2007/02/patenttestimony.shtm>. Visited on June 20, 2007.

See further the European Commission Communication, *A Pro-active Competition Policy for a Competitive Europe*, COM (2004) 293 final, available at http://europa.eu.int/lex/en/com/cnc/2004/com2004_0293en01.pdf. Visited on June 20, 2007;

the *‘DG Competition Discussion Paper on the Application of Article 82 of the Treaty to Exclusionary Abuses’*, available at <http://europa.eu.int/comm/competition/antitrust/others/discpaper2005.pdf>, and the EAGCP report *‘An economic approach to Article 82’* 2005, available at http://europa.eu.int/comm/competition/publications/studies/eagcp_july_21_05.pdf.

See also *Luc Peepkorn, DG Competition, unit A-1. ‘Commission publishes discussion paper on abuse of dominance’*, EC Competition Policy Newsletter, No. 1 – Spring 2006, pp. 4-7, available at <http://europa.eu.int/comm/competition/publications/cpn>. The most important topics raised in the public consultation process following the publication of the Discussion Paper were discussed in a *Public Hearing* in June 2006, see <http://ec.europa.eu/comm/competition/antitrust/art82/hearing.html>. Visited on 4th of February 2007.

One issue at the direct point of intersection, is the question how far a patent holder may go to defend his right against infringement. Since exclusivity is the essence of all IPRs, the owner of a patent may generally exclude others from infringing that patent. This includes the right to bring legal proceedings against a patent infringer to prevent or stop an infringement and to obtain a remedy in law.⁴ But if that right is used to harass competitors, the patent holder's right to enter into litigation can be questioned. In particular, it may be argued that if a dominant company acts in such an abusive way, antitrust concerns may motivate a curtailment of the right to bring a patent infringement action.

However, considering the dignity of the rights and interests at stake, such a statement is controversial on both sides of the Atlantic. Careful balancing is therefore necessary between the fundamental principle of access to the courts on the one hand, and the antitrust striving for normal or fair competition on the other. Moreover, though IPRs are not immune from antitrust intervention, it may be argued that the special features of IPRs must be taken into account when antitrust law is applied to them. The value of the IP at stake, the scope of legal protection that it is afforded, as well as its importance in the particular industry are thus factors that are not without consequence in the application of antitrust rules.⁵

In the United States (US), the traditional approach has been to ensure that antitrust immunity is conferred upon firms, including monopolists, that petition the government through lobbying, administrative procedures or litigation.⁶ However, litigation in which the court process is used as an anti-competitive weapon, is not protected. Rather, such anti-competitive conduct violates Section 2 of the *Sherman Act 1890*⁷ under three main theories. Under each theory, harassing patent infringement actions may thus be caught by antitrust law.⁸ Though not often successful, Section 2 claims based on anti-competitive patent enforcement litigation are becoming increasingly common.⁹

This can be contrasted with the situation in the European Community (EC), where the question whether, and in what circumstances, anti-competitive patent enforcement litigation should be able to constitute an abuse under Article 82 of the EC Treaty has still to be settled. However, a cautious and

⁴ Dieter Stauder, 'Enforcing Industrial Property Rights: Patent Protection From a Comparative Viewpoint' in: Christopher Heath and Anselm Kamperman Sanders (eds), *New Frontiers of Intellectual Property Law, IP and Cultural Heritage, Geographical Indications, Enforcement and Overprotection*, IIC Studies Volume 25 2005, p. 291.

⁵ Czapracka, pp. 24-5. See the *DG Competition Discussion Paper*, pp. 66-67, paras. 235-6.

⁶ *United Mine Workers v. Pennington*, 381 U.S. 657, 671-72 (1965); *E.R.R. v. Noerr Motor Freight*, 365 U.S. 127, 135-37, 145 (1961). See the *Noerr-Pennington Doctrine* below.

⁷ Section 2 of the Sherman Act, 15 U.S.C § 2, prohibits monopolization, see below.

⁸ See Balto and Wolman, pp. 74-80.

⁹ See Michael J. Meurer, 'Controlling Opportunistic and Anti-competitive Intellectual Property Litigation', 2003, 44 B.C. L. Rev. 509, p. 540 and Davies, Leburn & Stargard, 'Seeking the Right Balance to Maintain a Free Market', <http://howrey.com/docs/seekingtherightbalance.pdf>, p. 4.

strict approach has been taken in relation to *vexatious litigation* issues in general. Whilst recourse to a remedy in law cannot be deemed, of itself, to raise competition law concerns,¹⁰ the bringing of legal proceedings has, in *ITT Promedia*,¹¹ been held to be abusive in wholly exceptional circumstances. Provided two cumulative criteria are satisfied,¹² it thus appears that vexatious litigation can be contrary to Article 82 and thereby amount to an abuse of a dominant position.¹³ Till now, however, the case law on the matter is scarce, to say the least, and so far no cases have reached the European Court of Justice (ECJ).

Nevertheless, following the Commission's *AstraZeneca* decision,¹⁴ it seems that the EC may be taking on a more 'US style' approach in relation to anti-competitive enforcement litigation. At the very least, the Commission decision can be seen to have reaffirmed and clarified the earlier 'vexatious litigation doctrine' developed in *ITT Promedia*. However, the decision still leaves several important questions unanswered, hopefully to be clarified by the Court of First Instance (CFI) in the pending appeal.¹⁵ In the meantime, the many uncertainties surrounding the potential abuse are likely to impose a heavy burden on dominant undertakings, or undertakings that fear that they might be considered to be dominant. This is especially so in industries such as the pharmaceutical industry, in which IPRs are of particular significance and where infringement actions, and the threat of such actions, are commonplace.¹⁶ Unless and until the matter is finally settled and defined in EC law, undertakings in these industries will thus have to thread carefully indeed on what can be described as the 'patent infringement proceedings minefield'.¹⁷

¹⁰ See *Industrie des poudres sphériques SA v. Commission*, Case T-5/97 [2000] ECR II-3755, para. 213.

¹¹ *ITT Promedia v. Commission*, Case T-111/96 [1998] ECR II-2937, paras. 29-30, 54-62.

¹² See below.

¹³ See Steven Preece, 'Establishing an Abuse of Predatory Litigation', E.C.L.R. 1999, 20(2), 118-122; Alexander Böhlke, 'Monopolies and Market Dominance: Waiting for Modernisation', http://www.globalcompetitionreview.com/ear/11_monopolies.cfm, p. 2. Visited on June 12, 2006.

¹⁴ Commission Decision (COMP/37.507) of 15 June 2005.

Compare US 'improper Orange Book listings cases' brought by the FTC: *Biovail* (www.ftc.gov/os/2002/10/biovaildo.pdf) and *Bristol Myers Squibb* (www.ftc.gov/os/2003/03/bristolmyerscmp.pdf) in E.C.L.R. 2005, 26(12), 669-684, Gunther and Breuvert, 'Misuse of Patent and Drug Regulatory Approval Systems in the Pharmaceutical Industry: An Analysis of US and EU Converging Approaches', pp. 673 and 676-7. Visited on June 20, 2007.

¹⁵ Action brought on 25 August 2005, *AstraZeneca v. Commission*, Case T-321/05.

¹⁶ Richard Whish, 'Competition Law', 5th ed. 2003, p. 680.

¹⁷ Compare Ewan Nettleton and Brian Cordery, 'Walking the groundless threats minefield', J.I.P.L.P. 2005 Vol. 1, No. 1, p. 51 f.

Abbreviations

AG	Advocate General
AIPLA	American Intellectual Property Law Association
AZ	AstraZeneca AB/AstraZeneca Plc
CFI	Court of First Instance
COMPAT	Community Patent
CPC	Community Patent Court
Decision	Commission Decision from the 15 th of April 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 <i>AstraZeneca</i>)
Discussion Paper	Director General for Competition Competition Discussion Paper on the Application of Article 82 of the Treaty to Exclusionary Abuses
DoJ	Department of Justice
EAGCP	Economic Advisory Group for Competition Policy
EC	European Community
ECHR	European Convention of Human Rights
ECJ	European Court of Justice
EFPIA	European Federation of Pharmaceutical Industries and Associations
EPC	European Patent Convention
EPO	European Patent Office
EU	European Union
FDA	US Food & Drug Administration
FTC	Federal Trade Commission
Green Paper	Commission Green Paper on Damages Actions for Breach of the EC Antitrust Rules
Insurance Scheme	European Patent Litigation Insurance Scheme
IP	Intellectual property
IPR	Intellectual property right
NDA	New Drug Application
Orange book	Approved Drug Products with Therapeutic Equivalence Evaluations
PPI	Proton Pump Inhibitor
PTO	Patent and Trademark Office

R&D
SPC

STEP Board

Treaty

Research and Development
Supplementary Protection
Certificate

National Academies' Board on
Science, Technology, and
Economic Policy

Consolidated Version of the Treaty
Establishing the European
Community ([2002] OJ C 325/33)

1 Introduction

*'IP litigation may be expensive but, if you look after it properly, it will ultimately look after you.'*¹⁸

1.1 Objective

The aim of this thesis is to clarify (i) whether a '*vexatious litigation doctrine*' has come to exist under Article 82 EC, and if so, (ii) whether this development can be seen as evidence of an EC approach converging with that in the US in relation to the problem of anti-competitive patent litigation. These questions are topical for a number of reasons:

1. First and foremost because they involve issues at the very heart of *the intersection between IP and Competition Law*, a theme that continues to give rise to intense debate, both in the EC and the US.¹⁹ The fact that in the contemporary world, wealth and power reside less in hard assets than in IPRs has dramatically changed the forms under which acts of anti-competitive abuse take place today.²⁰ In addition, current trends in parts of the EC point towards an increased IP litigiousness that resembles the more aggressive litigation culture in the US.²¹ Will this turn into a Community problem to be tackled by Competition Law? If so, what are the consequences of such a view for innovation within the internal market?
2. Second, the recent Commission *AstraZeneca (AZ)* decision in June 2005, in which a €60 million fine was imposed on AZ for having abused its dominant position in relation to its anti-ulcer medicine ' Losec',²² can be seen to have brought new life into the earlier *ITT Promedia* decision and thus, arguably, to have revived the US style '*vexatious litigation doctrine*' presented in that case. AZ has appealed the Decision to the CFI,²³ and it will be interesting to see how the Court assesses the Commission's analysis in this respect.

¹⁸ J. Phillips, '*IP Litigation, the New Money Spinner*', J.I.P.L.P. 2006, Vol. 1, No. 8, 497.

¹⁹ See below.

²⁰ Jacques Werner, *Antitrust and Intellectual Property: The Uneasy Relationship*, The Journal of World Intellectual Property, 1999 2(3), 417-22, at 421-22.

²¹ See '*Patent Litigation Insurance – A Study for the European Commission on the Feasibility of Possible Insurance Schemes against Patent Litigation Risks*', Final Report June 2006, p. 13, available at http://ec.europa.eu/internal_market/indprop/patent/index_en.htm. Visited on February 3 2007.

²² See Commission Decision from the 15th of April 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*). The AstraZeneca decision is available at <http://ec.europa.eu/comm/competition/antitrust/cases/decisions/37507/en.pdf>.

²³ See notification of action brought by AstraZeneca on the 25th of August 2005 – AstraZeneca/Commission in case T-321/05, ([2005] OJ C 271/24).

3. Third, the *Discussion Paper* issued by the Director General for Competition of the European Commission in December 2005,²⁴ though not binding, has cast a considerable amount of light on the interpretation of Article 82 of the Treaty as well as on the methods likely to be applied by the Commission in the future. Surprisingly however, the document contains only one footnote reference to the important *AstraZeneca* decision and avoided any comment on the application of Article 82 EC to situations involving anti-competitive litigation.²⁵ Considering that one of the aims of the Article 82 review has been to increase the transparency, certainty and predictability, this may be criticised. It remains to be seen whether clarification will be achieved by the further steps expected to be announced in 2007.²⁶

4. Fourth, the topic is pertinent considering the plans to set up a *European Patent Litigation Insurance Scheme*. Ever since the reconsideration of the Patent system commenced in 1997 with the European Commission's Green Paper on the Community Patent and Patent System in Europe,²⁷ an insurance scheme has been one of the possibilities considered for making the patent system more attractive. A *Final Report* on patent litigation insurance was presented in June 2006,²⁸ commenting (albeit very briefly) on the potential problem of vexatious litigation.²⁹

5. Lastly, following the publication in December 2005 of the Commission's *Green Paper on Damages Actions for Breach of the EC Antitrust Rules* – aimed at facilitating private actions – the Commission is currently preparing a White Paper expected to be adopted in 2007.³⁰ Whether this will open the floodgates of litigation in the Community remains to be seen.

²⁴ See the Discussion Paper above, fn. 3.

²⁵ See Discussion Paper para. 60: 'Where a certain exclusionary conduct is clearly not competition on the merits, in particular conduct which clearly creates no efficiencies and which only raises obstacles to residual competition, such conduct is presumed to be an abuse.' Fn. 52: 'See for instance the recent Commission decision *AstraZeneca* of 15.06.2005'. See, however, a more elaborate general comment in the EC Competition Policy Newsletter, No. 1 – Spring 2007, '*Competition in Pharmaceuticals: the challenges ahead post AstraZeneca*', Nadia De Souza, DG for Competition, unit B-2, p. 39 f.

²⁶ See generally on the state of the Article 82 review,

<http://ec.europa.eu/comm/competition/antitrust/art82/index.html>. Visited on June 27, 2007.

²⁷ See COM(97) 314f.

²⁸ See '*Patent Litigation Insurance – A Study for the European Commission on the Feasibility of Possible Insurance Schemes against Patent Litigation Risks*', *Final Report* June 2006, p. 13, available at

http://ec.europa.eu/internal_market/indprop/patent/index_en.htm. Visited on 3rd of February 2007.

²⁹ See below.

³⁰ See *Green Paper Damages Actions for Breach of the EC Antitrust Rules*, Commission of the European Communities, COM (2005) 672 final. See also <http://ec.europa.eu/comm/competition/antitrust/actionsdamages/index.html>, visited on 3rd of February 2007. See also Chalmers, Hadjiemmanuil, Monti, Tomkins, '*European Union Law*', Cambridge University Press 2006, pp. 967-74.

For the just stated reasons it seems to be of high priority to analyse the scope of possible application of Article 82 EC to excessive patent litigation, and above all, to clarify where the line can be drawn between legitimate defence of business interests and illegitimate anti-competitive behaviour.

In order to do so, this thesis will examine the most recent EC developments in relation to *vexatious litigation as an abuse under Article 82*, with the aim of establishing the likely future significance of that article in the context of anti-competitive patent infringement actions. This will be done with particular focus on the Commission's *AstraZeneca* decision and the most recent steps taken in the Article 82 EC review process.

Following an overview of the basic law and policy of the EC and US antitrust and IP law regimes, EC and US case law will be compared to analyse to what extent there can be said to be a growing convergence in the respective approaches. Finally, an attempt will be made to anticipate future transatlantic policy approaches in relation to the IP and antitrust intersection.

1.2 Method & Material

In order to illustrate the author's view of the current legal position in EC law in relation to the application of Article 82 EC in the IP litigation context, a comparative legal research method was used to examine relevant EC and US legal material and case-law.

Information was acquired using relevant literature as well as various articles from journals and internet resources. Of particular importance was the *Discussion Paper*, the follow-up *Public Hearing* and, naturally, the Commission *AstraZeneca* decision.

Furthermore, internet was used to access legal acts of the European institutions. However, reference was made to the publications in the Official Journal. When referring to Articles in the Treaty, reference was made to the Treaty of Amsterdam numbering. The style of reference to the articles used corresponds with that used by the CFI and the ECJ.³¹

Decisions and other legal acts of the Commission were accessed over the internet and reference was made either to the relevant Official Journal or to the internet site. Similarly, case-law of the ECJ and CFI was analysed using documents available from the internet, but reference was made to the European Court Reports.

Finally, the necessary US material was acquired using relevant literature, journals and internet resources. When legal acts and decisions were accessed over the internet reference was made to the relevant internet site.

³¹ See Note on the Citation of Articles of the Treaties in the Publications of the Court of Justice and the Court of First Instance, ([1999] OJ C 246/1).

1.3 Delimitations

Even though some background information is presented in the thesis, it is assumed that the reader has basic knowledge of the European Union, the EC and US antitrust regimes as well as of the relevant IP regimes. Antitrust and IP law principles and provisions are presented and analysed only insofar as is needed to illustrate the particular issues relevant to the object of the thesis. Moreover, many important issues referred to are described only in such detail that it would enable the average legal professional who has knowledge of the relevant legal rules, to understand the presented arguments from an antitrust / IP intersection point of view.

As no access was had to the complete version of the *AstraZeneca* decision or to the file, the analysis was bound to be based on the non-confidential text of the Decision in the form it was made public, as well as on the notice about the appeal by AZ.³² Conclusions have been drawn based on the facts presented therein, which have been presumed to be correct.

Due to the relatively limited span of the thesis, the scope of analysis was necessarily reduced to the key questions relating to vexatious litigation as an abuse in the EC and US systems. Consequently, many interesting and closely linked legal issues that could have been included in a more thorough comparative analysis had to be left out.

³² The provisional version of the Commission Decision from the 15th of April 2005 (Case COMP/A.37.507/F3 *AstraZeneca*) as it was first made public is available at http://ec.europa.eu/comm/competition/antitrust/cases/decisions/37507/prov_version.pdf, (236 pages). A revised version is now available at <http://ec.europa.eu/comm/competition/antitrust/cases/decisions/37507/en.pdf>, (214 pages). Reference will be made to the recitals and page numbers in this latter version.

2 Striking the Balance between IP & Antitrust

The essential feature of what is generally referred to as the ‘New Economy’ is its increased dependence on products and services that are embodied in ideas. Hence, in several of the fastest growing segments of the present economy, the ‘product’ or ‘service’ is a piece of IP.³³

In these new markets, characterised by the presence of IP, antitrust enforcers are faced with special characteristics: incentives to innovate are particularly important, competition at the research and development (R&D) level is critical; markets are dynamic and market shares often unstable; predictions about market-development are uncertain; and the issues that enforcers must address are unusually complicated and technical.³⁴

A major challenge in the next decade is therefore to shape the policies that will best balance the two regimes and thus allow the market economy to thrive in the context of the ‘IP revolution’.³⁵

However, before making any attempt to strike a balance between IP and antitrust, it is necessary to examine their respective objects.

2.1 IP Law & Its Aim – The Economic Theory of Innovation

IP law can itself be said to carry out a balancing act – namely that between the need to give incentives for innovation with the interest of the public in having access to the products protected by the rights. Patent law can be viewed as the clearest example of this – the grant of the patent gives the owner a twenty-year monopoly of exploitation, but the trade off is that the details of the process are made public, so that at the end of the protection period everyone else gets access to it. Thus, the owner’s original monopoly enables him to reap the reward for the innovation but thereafter the public interest in access and dissemination takes over.³⁶

³³ See speech by Robert Pitofsky, Chairman of FTC, at the Antitrust, Technology and Intellectual Property Conference, March 2 2001, ‘*Antitrust and Intellectual Property: Unresolved Issues at the Heart of the New Economy*’, at <http://www.ftc.gov/speeches/pitofsky/ipf301.shtm>, visited on February 4 2007, p. 1.

³⁴ See speech by Pitofsky, pp. 5-6.

³⁵ See speech by Pitofsky, p. 1.

³⁶ The question is how far this inherent balancing act within IP law between incentives and access makes interference by competition laws on monopolies superfluous. Is there any need for competition law to control the exploitation of the rights when IP law takes care to strike a balance with the public interest? Whereas e.g. Govaere argues that ‘no additional restraints on IP owners need to be introduced in order to safeguard competition; it suffices to reinforce the restrictions inherent in the different types of IPRs’, Anderman argues that there is a role for competition law. See S. Anderman, ‘*EC Competition Law and Intellectual Property Rights*’ (1998); I. Govaere, ‘*The Use and Abuse of Intellectual Property Rights in E.C. Law*’ (1996).

Not surprisingly, the principal philosophical theory applied to justify the protection of utilitarian works such as technological inventions has been utilitarianism.³⁷ Economists on the other hand, have generally offered four principal incentive-based rationales for the existence of IPRs. These rationales, which include theories based on incentive, are also underlying the patent system's grant to the patent applicant of the right to exclude others from practicing an invention.³⁸

(i) First and foremost, the '*incentive to invent theory*' suggests that IPRs encourage invention. Under this theory, it is assumed that without the inducement of e.g. a patent, inventors might not invest sufficiently in the inventive process. For without IPRs, inventors might not be able to appropriate the full value of their inventions. 'Free riders' would be able to benefit from the results of innovation without actually investing in innovation themselves, which would decrease the incentive to invent.

(ii) Second, the '*incentive to disclose theory*' suggests that IPRs lead to the broader dissemination of innovations. Without the protection of IPRs, inventors would be forced to conceal their inventions in order to prevent free riding. A valuable source of teaching would thus disappear. Moreover, without the exclusivity and public announcement provided by a patent, wastefully duplicative expenditures could ensue. To avoid this, the patent laws offer a 'bargain' – they give the possibility of exclusivity, allow for licenses and give these value by protecting patents against infringement – in exchange, the patent applicant gives public disclosure of the IP in the patent application.

(iii) Third, the primary theory that focuses on organising post-inventive activity is called the '*prospect theory*'. Related theories focus on the incentive to invest, to innovate, or to commercialise – all of which aim at making an invention practicable and useful. According to these theories, IPRs lead to a greater commercialisation of inventions and encourage the licensing of those property rights to entities that are better able to exploit them in an economically efficient manner. For the prospect theory, the signalling function of the patent is crucial, as it is with the issuance that venture capitalists, developers, advertisers and sellers can all start making the necessary investments to ensure that consumers will eventually be offered the commercial embodiment of the invention.

(iv) Lastly, the '*incentive to design around theory*' suggests that there are advantages in encouraging competitors to circumvent a patent's scope by inventing substitutes. As a market for a patented product becomes increasingly successful, the patent provides an increasingly strong incentive for other players to invent non-infringing substitutes, or even infringing improvements. Patent rights thus assure the public availability of inventions with a strong potential for follow-on innovation. Though some argue that

³⁷ Peter S. Menell, '*Intellectual Property: General Theories*', 1999 University of California at Berkeley, 129-188, pp. 129-30. See also William Fischer, '*Theories of Intellectual Property*', 1-60, p. 2.

³⁸ Wendy J. Gordon in: *The Oxford Handbook of Legal Studies* (Chapter 28), Oxford University Press, edited by Peter Can and Mark Tushnet (October 2003) – Boston University School of Law, Working Paper Series, Law and Economics Working Paper No. 03-10, pp. 631-33. See also Balto and Wolman, pp. 22-24; Peter S. Menell, pp. 146-47.

such secondary inventive activity is largely superfluous, others claim that it is desirable in that second-generation products may be better than the first, whether it is because they are cheaper, more effective, or because they have fewer or different collateral costs or side-effects.

While agreeing on the rationales for the existence of IPRs, commentators disagree on the extent of IP protection that is desirable. Some of the potentially negative effects that the over extensive protection of IPRs may have on the economy are:³⁹

(i) IPRs may discourage second-generation innovation. As the cost of acquiring access to protected IP increases, the amount of research conducted using such property will decrease.

(ii) IPRs are a form of legalised monopoly, and as such it can be harmful to a competitive economy. To receive the greatest return, a monopolist will generally price at a level that excludes part of the market that is willing and able to pay above marginal cost for the product, with the effect that a deadweight loss is created.

(iii) Moreover, it has been observed that increasing the cost of information through IP protection will lead to dynamic inefficiencies in the economy. Market decisions will either not be fully informed or will be influenced by the cost of acquiring information.

(iv) Finally, IPRs can allow a company to leverage its possession of those rights in order to engage in anticompetitive behaviour or monopolisation beyond what is expressly allowed by the IP grant. Preventing this last negative economic effect from occurring is also one of the antitrust laws' greatest concerns in the IP context.

2.2 Antitrust Law & Its Aim – The Economic Theory of Competition

Ever since the enactment of the pioneering US 'antitrust laws' – most notably the *Sherman Act 1890* – and the later competition provisions in the *ECSC Treaty 1951*, there has been a considerable debate about the aims of competition law. Today, the majority view is that competition law should be enforced against firms whose behaviour harms consumers. The minority view, on the other hand, is that competition law can be enforced to attain a wider set of economic and non-economic ambitions. Some scholars – particularly those in the US – argue that competition law should be interpreted solely according to what economic theory dictates.⁴⁰ Irrespective of which view is the preferable, the debates on the appropriate aims of competition law have had, and continue to have, a significant impact on the shaping of the law in practice.⁴¹

³⁹Balto & Wolman, pp. 22-24.

⁴⁰R.H. Bork, *The Antitrust Paradox* (New York, The Free Press, 1978, reprinted 1993); R. A. Posner, *Antitrust Law* (2nd edn., Chicago, University of Chicago Press, 2000).

⁴¹Chalmers, Hadjiemmanuil, Monti, Tomkins, pp. 928-29.

For instance, although the role of economics was clearly insufficiently recognised in the early days of competition law in the EC, the general view today is that the theory and practice of competition law are inextricably tied to economics. Consequently, in the EC – admittedly with some delay compared to the US – the modern view of *competition policy as an economic policy concerned with economic structures, conduct, and effects*, has contributed to a growing awareness among competition policy makers of the importance of economics for their daily work.⁴²

Contemporary competition law enforcement is thus built upon an understanding of how markets work. Put simply, legal intervention should perform a twofold task: (i) *prohibit commercial practices that damage the operation of markets* and (ii) *promote activities that yield economic benefits*. Accordingly, a successful competition law is one that sustains an efficient economic order. While there is widespread disagreement on how such a competition law should be construed and enforced, economists tend to unanimously agree that competition legal norms are just as crucial to the modern economic order as the right to property and freedom of contract. Moreover, economists agree that there are three broad classes of efficiencies that are relevant for the analysis of competition. The first, ‘*allocative efficiency*’, means that resources are allocated to the production of goods and services in the way that society most values. The second type, ‘*productive efficiency*’, means that output is being produced at the lowest possible cost. ‘*Dynamic efficiency*’, finally, is connected to whether appropriate incentives and ability exist to increase productivity and engage in innovative activity over time, which may yield cheaper or better goods or new products that afford consumers more satisfaction than previous consumption choices.⁴³

The central concept in competition law, however, is ‘*market power*’ – the ability of a firm to exercise significant influence over price and output in a particular market over time.⁴⁴ While the general view is that market power may lead to allocative inefficiency and to a worsened productive efficiency, its impact on innovation is a lot more controversial.⁴⁵

In the US, two schools of economists have dominated antitrust thought – the Harvard and Chicago schools, developed in the 1960s and 1970s respectively. The *Harvard school* was born out of the conviction that undertakings that have market power are likely to act inefficiently and that competition law therefore must be enforced against them.⁴⁶

The *Chicago scholars* on the other hand, believe that the fundamental goal/sole pursuit of antitrust is, or ought to be, the pursuit of efficiency, or

⁴² Whish, p. 1; Kirsty Middleton, ‘*Cases and Materials on UK and EC Competition Law*’, Oxford University Press 2003, p. 17.

⁴³ Whish, p. 1078; Chalmers, Hadjiemmanuil, Monti, Tomkins, pp. 929-30.

⁴⁴ Whish, p. 1080.

⁴⁵ Chalmers, Hadjiemmanuil, Monti, Tomkins, p. 930.

⁴⁶ According to these scholars, a direct causal link exists between market structure and economic performance, whereby the fewer the firms and thus the more concentrated the market, the less competitive the industry is bound to be. Chalmers, Hadjiemmanuil, Monti, Tomkins, p. 933.

rather the maximisation of allocative efficiency. According to this view, consumer welfare is optimised in free markets. Even monopolistic markets are acceptable and state intervention is required only in extreme cases where new entrants are prohibited from the market.⁴⁷

Obviously, the views represented by the two schools diverge significantly in their prescriptions for competition law enforcement. Although the Chicago School has so far been regarded as the most influential, that model is currently being contested by ‘post-Chicagoans’ and their economic theories. Unlike the Chicago scholars, the *post-Chicago economists* believe that market failures are not necessarily self-correcting, and that firms therefore can take advantage of imperfections to produce inefficient results even in apparently competitive markets.⁴⁸ Consequently, they argue that these distortions to competition legitimise scrutiny of a wider variety of conduct than the traditional Chicago school does. Moreover, while Chicagoans presuppose that markets promote efficient business behaviour and that judges are ill-equipped to identify and assess market imperfections, post-Chicagoans have less trust in markets and more confidence in the judiciary’s ability to distinguish between competitive and anticompetitive conduct.⁴⁹

That task is particularly challenging when it comes to realising *dynamic efficiency* in today’s society. On the one hand, an inefficient market structure today might be the only way to have future inventions tomorrow. For even though one might e.g. object to a monopolised pharmaceutical sector, it may be necessary to concentrate resources to obtain important drugs in the future. On the other hand, one may question to what extent competition today must be hampered in favour of greater consumer benefits tomorrow. For although some argue that the frequent innovations that occur in high technology markets mean that competition law should not be overly concerned about monopolies in such markets, others have taken the view that innovation can and will occur only if new entrants are protected by competition law regulating the firms that monopolise the market.

Despite the fact that antitrust economists agree that net efficiency gains from continuing innovation may far outweigh the static gains from marginal-cost pricing, no consensus exists as to the best competition policy to facilitate innovation. Consequently, competition authorities are left with the task of choosing which means are best to maximise dynamic efficiency ‘in a climate where economics provides no clear answer’.⁵⁰

In carrying out this task, EC competition law was in its early years strongly influenced by the so-called ‘*ordoliberal*’ economic philosophy. Under this theory, the process of competition is valued and access and opportunities for new businesses favoured. Concern about economic power should therefore

⁴⁷ Middleton, pp.5-6.

⁴⁸ Whilst ‘Chicagoans’ assume that the desire to maximise profits makes market imperfections disappear of themselves in the competitive process, ‘post-Chicagoans’ believe that strategising firms can create or maintain market imperfections that can seriously hinder the competitive balance.

⁴⁹ Chalmers, Hadjiemmanuil, Monti, Tomkins, pp. 932-34.

⁵⁰ *Id.*

lead competition authorities to intervene even if it would not result in the most efficient outcome. Article 82 of the EC Treaty, forbidding the abuse of market power by dominant firms, is a clear illustration of this concern about economic power. For a long time this view stood uncontested in the Community legal order. EC competition law was to serve a sole political objective – the preservation of the competitive process – and other goals were to be obtained by enforcing competition law.⁵¹

However, as the EC transformed into a ‘neoliberal’ market economy, the increased emphasis on the benefits of efficient markets undermined the ordoliberal concerns about economic power. The current approach in the EC is best summarised by the speech recently held by the current Competition Commissioner Neelie Kroes: ‘Consumer welfare is now well established as the standard the Commission applies when assessing mergers and infringements of the Treaty rules on cartels and monopolies. Our aim is simple: to protect competition in the market as a means of enhancing consumer welfare and ensuring an efficient allocation of resources. An effects-based approach, grounded in solid economics, ensures that citizens enjoy the benefits of a competitive, dynamic market economy.’⁵²

2.3 IP & Antitrust – The Right Balance

As illustrated above, the IP laws provide incentives for innovation and its dissemination and commercialisation by establishing enforceable property rights for the creators of new and useful products. The antitrust laws, on the other hand, promote innovation and consumer welfare by prohibiting certain actions that may harm competition.⁵³

Competition and patents are thus not inherently in conflict. Although ‘the aims and objectives of patent and antitrust laws may seem, at first glance, wholly at odds [...] the two bodies of law are actually complementary, as both are aimed at encouraging innovation, industry and competition.’⁵⁴

While IPRs subsidise investments in innovation by granting substantial but time-limited market power, antitrust ensures that firms compete, and by competing, seek new roads to innovation. It also prevents dominant firms from harming or retarding innovation.⁵⁵

⁵¹ Chalmers, Hadjiemmanuil, Monti, Tomkins, pp. 935-36.

⁵² Speech on 15 Sept. 2005, ‘*European Competition Policy: Delivering Better Markets and Better Choices*’, available at http://europa.eu.int/comm/competition/index_en.html. See also Chalmers, Hadjiemmanuil, Monti, Tomkins, pp. 936-38.

⁵³ US DoJ and FTC ‘*Antitrust Guidelines for the Licensing of IP*’ (1995), available at <http://www.usdoj.gov/atr/public/guidelines/0558.pdf>, p. 2. Visited on June 20, 2007.

⁵⁴ See *Atari Games Corp. v. Nintendo of Am.*, 897 F.2d 1572 (Fed. Cir. 1990) in the US DoJ and FTC 1995 *IP Guidelines*, p. 2. and the 2003 FTC report, ‘*To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy*’ – Executive Summary, available at <http://www.ftc.gov/os/2003/10/innovationrptsummary.pdf>, p. 2. Compare Section 7 of the 2004 *EC Guidelines on Technology Transfer Agreements* (Official Journal C 101 of 27.04.2004) available at http://eur-lex.europa.eu/LexUriServ/site/en/oj/2004/1_123/1_12320040427en00110017.pdf, recognising that there is no ‘inherent conflict between [IPRs] and the Community competition rules’ as ‘both bodies of law share the same basic objective of promoting consumer welfare and an efficient allocation of resources’. Visited on June 20, 2007.

⁵⁵ See speech by Robert Pitofsky, p. 5.

Both competition and patent law and policy can thus stimulate innovation and benefit the public, but they must work together in a proper balance to do so. Errors or system biases in how one policy's rules are interpreted and applied can harm the other policy's effectiveness.⁵⁶ To avoid the serious problems that are bound to arise when either regime is accorded disproportionate weight, it is thus essential that the balancing act continues and is regularly made subject of review.⁵⁷

In October 2003, after extensive hearings, the FTC issued the first of two reports on how to promote innovation by finding the proper balance between competition and patent law and policy. This *2003 FTC Report* contains conclusions and recommendations addressing the patent system.⁵⁸ The report concluded that questionable patents are a significant competitive concern and can harm innovation. The report made ten recommendations for reducing the number of questionable patents that are issued and upheld.⁵⁹ In 2004 a further report was produced by *National Academies' Board on Science, Technology, and Economic Policy* (STEP), as well as position papers by the *American Intellectual Property Law Association* (AIPLA).⁶⁰ In October 2004, *DoJ's Task Force* on Intellectual Property released a *Report on Intellectual Property*.⁶¹ Apart from recommending three interesting antitrust initiatives,⁶² the report identified key principles shaping the DoJ's IP enforcement efforts as well as providing a basis for recommending further actions.⁶³

⁵⁶ See report by the FTC, '*To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy*' – Executive Summary, p. 1.

⁵⁷ See speech by Robert Pitofsky, p. 5.

⁵⁸ The report – '*To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy*' – is available at <http://www.ftc.gov/os/2003/10/innovationrpt.pdf>. Visited on June 20, 2007. The second, joint report by the FTC and DOJ, which should make similar recommendations for antitrust law has not yet been issued.

⁵⁹ The FTC's 10 recommendations included the following;

To increase a challenger's ability to eliminate questionable patents, legislation should be enacted to create a new administrative procedure to allow post-grant review of and opposition to a patent after it is issued.

To promote the disclosure function of patents, legislation should be enacted to require, as a predicate for liability for wilful infringement, either written notice of infringement from the patentee or deliberate copying of the patentee's invention, knowing it to be patented.

⁶⁰ The *STEP Board Report 2004: 'A Patent System for the 21st Century'* is available at <http://www.nap.edu/html/patentsystem>. See also AIPLA at <http://www.aipla.org>. Visited on June 20, 2007.

⁶¹ See *DoJ's Task Force Report on Intellectual Property 2004*, available at <http://www.usdoj.gov/criminal/cybercrime/IPTaskForceReport.pdf>. Visited on June 20, 2007.

⁶² First, it supported the right of IP owners to determine independently whether or not to license their technology. Second, it encouraged the use of the DoJ's business review procedure for guidance on antitrust concerns relating to industry standards for the prevention of IP theft. Lastly, it suggested that international co-operation on the application of antitrust laws to IPRs be promoted. See DoJ Report, pp. 41-5.

⁶³ For instance, it was stressed that the government and IP owners have a collective responsibility to take action against violations of federal IP laws & that the federal government should punish those who misuse innovative technologies rather than innovation itself. See the DoJ Report, pp.11-12.

Following the FTC 2003 Report, the 2004 STEP Board Report and the AIPLA position papers, a series of *patent hearings* were organised in 2005 in order to initiate a discussion among all stakeholders in the patent system on the content of needed reforms.⁶⁴ All parties concluded that the patent system would benefit from some form of post-grant review. As the Report had observed, litigation removes invalid patents only slowly and at great cost; challengers cannot seek declaratory judgments until imminently threatened with suit. Taken together with the fact that ‘patent litigation is lengthy and expensive’,⁶⁵ those considerations suggested that ‘some unwarranted patents will be issued and will remain factors in the market for considerable time. They may create unnecessary market power and transaction costs and infect markets with risk, uncertainty, and distorted business planning.’⁶⁶

In a testimony in February 2007, the FTC further emphasised that invalid or questionable patents can increase costs and hinder competition.⁶⁷ Implementing the patent reform recommendations the agency made in its 2003 report would increase the likelihood that issued patents are valid, and that challenges to invalid patents will proceed more efficiently.

Since 2004 and the European Commission’s Communication ‘*A pro-active Competition Policy for a Competitive Europe*’ the aim of developing competitive, innovative markets has been at the head of the EC agenda.⁶⁸ Naturally, the Commission is therefore conscious of the need to balance competition and innovation. The IP-antitrust interplay is also an important aspect of the overall *Article 82 review process*.⁶⁹

⁶⁴ See <http://www.ftc.gov/opa/2005/06/patentconference.shtm>, visited on June 20, 2007. Themes of discussion included: establishment of a system of post-grant review within the PTO to weed out questionable patents; limiting litigation over wilful infringement in order to foster dissemination of information about inventions; and expanding publication of patent applications to avoid harm to competition and to facilitate rational business planning.

⁶⁵ The *STEP Board Report 2004*, at 68, notes that litigation ‘typically costs millions of dollars and takes years to resolve. The median costs to each party of proceeding through a patent infringement suit to a trial verdict are at least \$500,000 when the stakes are relatively modest. When more than \$25 million is at risk in a patent suit, the median litigation costs for the plaintiff and the defendant average \$4 million each, and in the highest-stakes patent suit, costs can exceed this amount by more than fivefold.’

⁶⁶ See speech available at <http://www.ftc.gov/speeches/majoras/050609compolicy.pdf>. Visited on June 20, 2007.

⁶⁷ According to the testimony (February 15, 2007), patents of questionable quality can distort competition, innovation, and the marketplace in at least four ways: 1) They may slow innovation by discouraging companies from conducting research and development in areas that the patent improperly covers; 2) patents that should not have been granted raise costs when they are challenged in litigation; 3) questionable patents may raise costs by inducing unnecessary licensing; and 4) firms facing overlapping patent rights may spend resources obtaining ‘defensive patents,’ not to protect their own innovation from use by others, but to have ‘bargaining chips’ to obtain access to others’ patents through a cross-license, or to counter allegations of infringement. The testimony is available at <http://www.ftc.gov/opa/2007/02/patenttestimony.shtm>. Visited on June 20, 2007.

⁶⁸ See European Commission Communication, ‘*A Pro-active Competition Policy for a Competitive Europe*’, COM (2004) 293 final, available at http://europa.eu.int/lex/en/com/cnc/2004/com2004_0293en01.pdf. Visited on June 20, 2007.

⁶⁹ See below.

3 The Patent Laws

As stated above, '[t]he central function of IPRs is to protect the moral rights in a right-holder's work and ensure a reward for the creative effort.'⁷⁰ IPRs generally – and the patent grant particularly – reward invention and innovation and thus function to encourage investment in the discovery of new technologies. 'From the composition of a new drug to the latest time-saving gadget, patents protect the world of inventions.'⁷¹

The patent grant, which is intended to increase the perceived financial reward from investments, does so by offering the investor the monopoly, for a maximum period of twenty years from the date when patent application is filed,⁷² to exploit the new and inventive product or process. The investor is thus given the right to prevent others from making, disposing of, using or importing a product, which is the subject of the patent or derived from it, or from using the patented process itself.

Without such protection, free-riders that have not made the investment that resulted in discovery of the technology would be able to appropriate much of its value at the expense of the investor. The exclusive patent grant eliminates the deterrent effect of such free-riding, as well as increases the likelihood that the profits of research which come to fruition can cover the costs of that which does not. Even though the right to exclude is made contingent on a full disclosure of the details of the invention in the patent specification to any interested member of the public, the right to exclude thus enables the investor to appropriate much of the value to society that results from the technological advance.⁷³

That patents are a driving force for promoting innovation, growth and competitiveness is common ground on both sides of the Atlantic. Both legal systems have thus aimed at modelling patent systems that will yield the most added value for their industries. However, so far the unified US federal patent law system stands in stark contrast to the fragmented EC system, where a Community-wide patent still shines with its absence.

3.1 Patents in the EC System

Recent figures show that the incomplete single market for patents has serious consequences for the competitiveness of Europe in relation to the challenges of the US, Japan and emerging economic powers such as China. That the Community is clearly lagging behind in terms of patent activity

⁷⁰ Case COMP/C 3/37.792 *Microsoft-Antitrust* [2004] EC Comm. 1, para. 711.

⁷¹ See the DoJ's Task Force Report on IP, October 2004, p. 3.

⁷² The term of a US patent is generally 20 years. Patent term extensions or adjustments may be available for pharmaceuticals. The maximum 20 years is also common throughout the EU. In relation to pharmaceuticals, Council Reg. 1786/92, [1992] OJ L182/1, on the creation of supplementary protection certificates for medical products enables a period not exceeding five years to be added to this in respect of the period between the date of filing the application and the grant.

⁷³ See Alison Jones and Brenda Sufrin, '*EC Competition Law – Texts, Cases and Materials*', Oxford University Press 2001, p. 557 and Balto & Wolman, p. 25.

becomes evident when one considers that even in Europe, the US and Japan patent more than the EC. Moreover, the figures show that a European patent designating 13 countries is 11 times more expensive than a US patent and 13 times more expensive than a Japanese patent if processing and translation costs are considered. For the total costs with up to 20 years of protection, European patents are nearly nine times more expensive than Japanese and US patents. Moreover, the existing system of patent litigation, with the risk of multiple patent litigation in several countries on the same patent issue, leads to unnecessary costs for all parties involved and causes lack of legal certainty. Hence, there is an urgent need for action.⁷⁴

3.1.1 The Current Order

Although the indispensability of a patent system to the economic wellbeing of Europe is generally recognised within the Community, all attempts to achieve consensus on the creation of a 'Community Patent' (COMPAT) have so far proved unsuccessful. The idea of a COMPAT, which would allow individuals and companies to obtain a unitary patent throughout the EC, dates back to the 1960s, but has repeatedly failed due to what must be lack of political will on the part of the Member States.

Today, therefore, common patent rules exist only in certain areas such as biotechnology and pharmaceuticals, and patents within the EC are still awarded either on a national basis or through the European Patent Office (EPO). The EPO, which is not an agency of the EU but an autonomous body with 31 member states, was established in 1973 by the *European Patent Convention* (EPC), to issue so-called 'European Patents'. These are not Europe-wide patents, but rather represent bundles of national patents that must be translated into the contracting states' official languages in order to be legally valid in their territory. Once granted, the protection is then dependent on the national patent rules in each one of the selected countries. Despite the fact that there is a single application and granting procedure, which saves some time and money for applicants, the EPC system has deficiencies in that it – apart from significant translation costs – generates large enforcement costs for businesses, as disputes must be handled via individual national courts.⁷⁵

3.1.2 The Future Order

In follow-up to the Lisbon Council, which outlined a ten-year plan to make the EU more competitive, the Commission, in July 2000, proposed the creation of a Community Patent to tackle the weaknesses of the EPC

⁷⁴ See the 'Communication from the Commission to the European Parliament and the Council – Enhancing the patent system in Europe', Brussels, COM (2007) 29-03-07, pp. 2-3. Available at http://ec.europa.eu/internal_market/indprop/docs/patent/strategy_en.pdf, visited on April 4th 2007. See also the Commission's Press Release 'Patents: Commission sets out vision for improving patent system in Europe', available at <http://europa.eu/rapid/pressReleasesAction.do?reference=IP/07/463&type=HTML&aged=0&language=EN&guiLanguage=fr>, visited on the 4th of April 2007.

⁷⁵ See <http://www.euractiv.com/en/innovation/community-patent/article-117529>, visited on April 4 2007.

system. However, as many times before, the creation process reached a state of stagnation and it was to take the Member States until March 2003 to reach agreement on a 'common political approach' concerning the establishment of a Community Patent Court (CPC) which would rule on disputes, language regimes, costs and the role of national patent offices. In December 2003, the Commission then presented a proposal to confer formal jurisdiction over COMPAT disputes to the ECJ and to establish a CPC to exercise the ECJ's jurisdiction on its behalf. However, the proposal never received Council's approval.⁷⁶

The difficulties in making progress on patents and especially on the creation of a COMPAT led the Commission to launch, in 2006, a *Consultation* on the future patent system, the results of which in the Commission's words 'leave no doubt on the urgent need for action to provide a simple, cost-effective and high-quality patent system in Europe, both for examination and grant as well as post-grant procedures, including litigation'.⁷⁷

Recently, in yet another attempt to revitalise the debate on the issue, the Commission has set out its vision on how to improve the patent system in a *Communication*.⁷⁸ Making the COMPAT a reality and improving the existing patent litigation system are two steps that are thought to make the patent system more accessible and bring cost savings for all. Above all, it is thought to better equip Europe for the competitive climate in today's increasingly competitive global economy. 'Europe [simply] cannot afford to lose ground in an area as crucial as patent policy.'⁷⁹

If (or when) it becomes reality, the COMPAT would allow individuals and companies to obtain a unitary patent throughout the European Union. Unlike the European Patents under the EPC, which once granted, constitute a bundle of nationally enforceable patents in the designated states, the COMPAT would provide a patent right that is consistent across Europe. This would further one of the objects of the internal market – namely that the same market conditions should exist wherever in Europe trade is carried out. Until this aim is achieved, the single market for patents arguably remains incomplete.⁸⁰

⁷⁶ See <http://www.euractiv.com/en/innovation/community-patent/article-117529>, visited on April 4 2007. See also generally

http://ec.europa.eu/internal_market/indprop/patent/index_en.htm, visited on June 20, 2007.

⁷⁷ See the Commission's Press Release '*Patents: Commission sets out vision for improving patent system in Europe*', Reference : IP/07/463; Date: 03/04/2007. Available at <http://europa.eu/rapid/pressReleasesAction.do?reference=IP/07/463&language=EN>. See also consultation documents available at

http://ec.europa.eu/internal_market/indprop/patent/consultation_en.htm.

⁷⁸ See the Communication from the Commission to the European Parliament and the Council – '*Enhancing the Patent System in Europe*' COM(2007) 165 final, available at http://eur-lex.europa.eu/LexUriServ/site/en/com/2007/com2007_0165en01.pdf.

The Patent Communication is intended to draw operational conclusions from the stakeholder consultation and to allow the Council to launch deliberations on patent reforms, in particular on the Community patent and jurisdictional arrangements. A complementary but separate and comprehensive IPR Communication is planned for 2008, to address outstanding non-legislative and horizontal issues in all fields of IP.

⁷⁹ See Press Release IP/07/463.

⁸⁰ In view of the difficulties in reaching an agreement on the COMPAT, other legal agreements have been proposed outside the EU legal framework to reduce costs, namely *the Agreement dated 17 October 2000 on the application of Article 65 of the Convention on*

3.2 Patents in the US System

The *Constitution of the United States* gives the US Congress the power to enact laws relating to patents. According to Article I, Section 8, Clause 8 ‘Congress shall have power...[t]o promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries.’⁸¹

Since the first Patent Act was enacted in 1790, the US Congress has enacted various laws relating to patents under this power. A general revision of the patent laws came into effect in 1953 and was codified in *Title 35, United States Code* (U.S.C.). Additionally, in 1999, Congress enacted the *American Inventors Protection Act* (AIPA), which further revised the patent laws.⁸²

US Patents are issued by the *Patent and Trademark Office* (PTO). Generally, the term of the patent is 20 years from the date on which the application for the patent was filed in the US (or, in special cases, from the date an earlier related application was filed, subject to the payment of maintenance fees). However, just like in the EC, patent term extensions or adjustments may be available under certain circumstances.⁸³ US patent grants are effective only within the United States, its territories and possessions.⁸⁴

3.2.1 The Current Order

As the *Patent Act* provides ‘[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.’⁸⁵

Taken together, the patentable classes of subject matter include practically everything that is made by man and the processes for making the products.⁸⁶

However, the patent law specifies that the subject matter must be *useful*, meaning that the subject matter must have a useful purpose and operativeness. Moreover, interpretations of the statute by the courts have defined the limits of the field of subject matter that can be patented so that

the Grant of European Patents (the London Agreement) and *the Draft Agreement on the establishment of a European patent litigation system* (the draft European Patent Litigation Agreement (EPLA)).

⁸¹ Balto & Wolman, p. 24.

⁸² See ‘*General Information Concerning Patents*’ provided by the US PTO, available at <http://www.uspto.gov/web/offices/pac/doc/general/index.html#patent>, visited on April 5 2007.

⁸³ The terms may be extended for certain pharmaceuticals and for certain circumstances as provided by law.

⁸⁴ See PTO – General Information.

⁸⁵ *Id.* and 35 U.S.C. § 101. See also Balto & Wolman, p. 24.

⁸⁶ Three types of patents may be granted: 1) Utility patents may be granted to anyone who invents or discovers any new and useful process, machine, article of manufacture, or composition of matter, or any new and useful improvement thereof; 2) Design patents may be granted to anyone who invents a new, original, and ornamental design for an article of manufacture; 3) Plant patents may be granted to anyone who invents or discovers and asexually reproduces any distinct and new variety of plant. See PTO – General Information.

the laws of nature, physical phenomena, and abstract ideas are not patentable subject matter.⁸⁷

In order for an invention to be patentable it must be new or *novel* as defined in the patent law, which provides that an invention cannot be patented if: ‘(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent,’ or

‘(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country more than one year prior to the application for patent in the United States [...]’⁸⁸

Even if the subject matter sought to be patented is not exactly shown by the prior art, a patent may nevertheless be refused if the subject matter sought to be patented is not sufficiently different from what has been used or described before. In other words, it must be *non-obvious* to a person having ordinary skill in the area of technology related to the invention.⁸⁹

Two sections of the *Patent Act* collectively represent the foundation that grants patent owners a legal monopoly over their inventions; The first of the two central sections is 35 U.S.C. § 154, which states that ‘[e]very patent shall contain [...] a grant to the patentee [...] the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States [...]’

The second section is 35 U.S.C. § 271(d), which states that ‘[n]o patent owner otherwise entitled to relief [...] shall be denied relief or deemed guilty of misuse or illegal extension of the patent right by reason of his having [...] refused to license or use any rights to the patent [...]’

From this follows that the IPR conferred on the inventor by the patent grant is *the right to exclude* others from making, using, offering for sale, selling or importing the invention during the protection period.⁹⁰ Hence, patent owners can restrict others' access to their inventions, or even exclude others from their inventions entirely, without violating the law.⁹¹

Still, a patentee is not authorised to make, use, offer for sale, or sell, or import the invention if doing so would violate any law. One such limitation is that a patentee may not infringe another's patent, which is still in force. Another is that a patentee may not violate the federal antitrust laws by virtue of having a patent.⁹²

⁸⁷ Id.

⁸⁸ Id. Thus, if the invention has been described in a printed publication anywhere in the world, or if it was known or used by others in this country before the date that the applicant made his/her invention, a patent cannot be obtained. Nor can a patent be obtained if the invention has been described in a printed publication anywhere, or has been in public use or on sale in the U.S. more than one year before the date on which an application for patent is filed in there. In this connection it is immaterial when the invention was made, or whether the printed publication or public use was by the inventor himself/herself or by someone else.

⁸⁹ See PTO – General Information.

⁹⁰ Balto & Wolman, p. 24.

⁹¹ Barry M. Visconte, ‘A Bitter Pill to Swallow: Patent Law, A True Exception to Antitrust Law – *Schor v. Abbott Laboratories*’, 75 U. Cin. L. Rev. 399, 2006 University of Cincinnati, pp. 403-404.

⁹² See PTO – General Information.

3.2.2 The Future Order

The well developed and unified US patent system obviously faces very different problems and challenges than those faced by the European Community. For instance, whereas reforms in the EC aim at increasing patent activity and reducing costs, recent reform proposals in the US are directed at preventing the issuing of invalid or questionable patents. In particular, the *2003 FTC Report* contains important conclusions and recommendations addressing the patent system.⁹³ It may be expected that a system of post-grant review within the PTO will be established in the near future.⁹⁴

⁹³ The report – ‘*To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy*’ – is available at <http://www.ftc.gov/os/2003/10/innovationrpt.pdf>. Visited on June 20, 2007.

⁹⁴ See the FTC testimony available at <http://www.ftc.gov/opa/2007/02/patenttestimony.shtm>. Visited on June 20, 2007.

4 The Competition & Antitrust Laws

Both the US and EC systems rest on the idea that enterprises holding significant market power should be subject to considerable scrutiny by competition authorities. The economic explanation behind this idea is that dominant firms generally have the kind of economic power that tends to reduce efficiency, in particular where there are no competitive pressures to prevent them from raising prices and reducing output. In addition, there are persuasive policy arguments in favour of preventing large firms from exercising their market power to consolidate their dominance, or even to expand their influence into the political domain.⁹⁵

4.1 Competition Law in the EC

The creation of a single market has been the overriding aim of the Community since its inception and the commitment to free market principles is evidenced throughout the Treaties.⁹⁶

The basis for the EC competition law regime may be found in Articles 2 and 3 (1) (g) of the Treaty. Article 2, in which the main objectives of the Community are articulated, states that the ‘Community shall have as its task, by establishing a common market [...] to promote throughout the Community a harmonious, balanced and sustainable development of economic activities’ and ‘a high degree of competitiveness’. Article 3 then lists the means necessary to achieve the goals in Article 2 and requires in paragraph (g) the institution of ‘a system ensuring that competition in the common market is not distorted’.

The competition rules themselves can be found in Articles 81-86 of the EC Treaty, which apply to undertakings, private and public. The cornerstones of Community competition policy are Articles 81 and 82 EC. Whereas Article 81 is concerned with agreements, decisions and concerted practices which have an anticompetitive object or effect, Article 82 is directed towards the unilateral conduct of dominant firms which act in an abusive manner. These articles, which are not mutually exclusive, complement the free movement of goods provisions.⁹⁷

Of particular importance for a proper understanding of the Community competition law is the ECJ’s teleological interpretation of the Treaty, whereby it consistently applies the competition rules against the background of the overall objectives expressed in Article 2 and 3 (1) (g). This has been highly significant in the cases involving anti-competitive abuses.⁹⁸

⁹⁵ Chalmers, Hadjiemmanuil, Monti, Tomkins, p. 1024.

⁹⁶ Compare the Ninth Report on Competition Policy (1980) pp. 9-12, which remains an authoritative view of the policy objectives of Community competition policy.

⁹⁷ Whish, p. 175. See also Middleton, pp. 14-17.

⁹⁸ Whish, p. 194.

4.1.1 Art. 82 EC – Abuse of a Dominant Position

In the Community, dominant firms are subject to Article 82 EC, the primary purposes of which is to prevent businesses which possess power through their position on the market from distorting competition within the internal market. The provision can be seen as supporting the four freedoms from the damaging effects, which may be caused by the use and abuse of market power within the Community. The prohibition of the ‘abuse’ of this power is set out in Article 82 EC, which stipulates that:⁹⁹

‘Any abuse by one or more undertakings of a dominant position within the common market or in a substantial part of it shall be prohibited as incompatible with the common market in so far as it may affect trade between Member States.

Such abuse may, in particular, consist in:

- (a) directly or indirectly imposing unfair purchase or selling prices or other unfair trading conditions;*
- (b) limiting production, markets or technical development to the prejudice of consumers;*
- (c) applying dissimilar conditions to equivalent transactions with other trading parties, thereby placing them at a competitive disadvantage;*
- (d) making the conclusion of contracts subject to acceptance by the other parties of supplementary obligations which, by their nature or according to commercial usage, have no connection with the subject of such contracts.’*

In the EC, Article 82 EC thus represents one of the pillars in the system ensuring that competition in the internal market is not distorted. By encouraging ‘competition on the merits’, and by stimulating and awarding businesses that strive to satisfy consumer needs, the EC system seeks to ensure that superior business performance is the sole factor determining the success of an undertaking and that the most efficient use of resources is attained. Article 82 EC thus aims at protecting the competitive process and thereby the opportunities of competitors to compete on the merits.

However, this objective and the efficiencies thought to be associated with genuine undistorted competition, are clearly not end goals in themselves. Rather, they are pursued for the benefit of the consumers, who are to be protected not only from direct harm, but also from practices detrimental to them through their impact on the effective competition structure.¹⁰⁰ This was emphasised in the recent *Discussion Paper on exclusionary abuses*, according to which ‘the objective of Article 82 is the protection of competition on the market as a means of enhancing consumer welfare and of ensuring an efficient allocation of resources. Effective competition brings benefits to consumers, such as low prices, high quality products, a wide selection of goods and services, and innovation. Competition and market integration serve these ends since the creation and preservation of an open single market promotes an efficient allocation of resources throughout the Community for the benefit of consumers.’¹⁰¹

⁹⁹ Middleton, p. 297.

¹⁰⁰ See Case 6/72 *Europemballage Corporation and Continental Can Company Inc. v Commission of the European Communities*, [1973] ECR 215 para. 26.

¹⁰¹ Discussion Paper, para. 4.

Having looked at the aims and objectives of the Article, the following sections will focus on the different components that need to be satisfied for there to be ‘an abuse of a dominant position’. To establish an infringement of Article 82 EC, it must be shown that:¹⁰²

- (i) an undertaking is *dominant* in a given market
- (ii) it has *abused* its dominant position
- (iii) the abuse has had an *effect on trade* between Member States
- (iv) there is an *absence of a defence*

4.1.1.1 Dominance in the Relevant Market

For the purposes of Article 82, it is vital to ensure that an undertaking, which is suspected of abusing its dominant position, does indeed have market power. For without that dominance or market power, the undertaking will be naturally constrained by its competitors and antitrust intervention is unnecessary.¹⁰³ However, since a dominant position always exists in relation to a certain market,¹⁰⁴ a finding of market power cannot be established without first determining in which market the undertaking operates.

Market Definition – In response to the criticism directed at the Commission’s arguably arbitrary, unsophisticated, economically indefensible and overly narrow approach to market definition, a *Notice on market definition* was published in 1997.¹⁰⁵ The Notice, which is not a legally binding market definition code, sought to introduce a new, more objective and transparent standard for defining the relevant market as well as a more economically-oriented methodology to market definition. Considering that the same approach to market definition should be taken regardless of the type of competition law inquiry, it plays an important role for all EC competition law.¹⁰⁶ This was confirmed in the *Discussion Paper*, which states that the *Notice* should serve as the basis for market definition issues also for the application of Article 82 EC.¹⁰⁷

Market definition, as described in the *Notice*, is a tool to establish the framework within which competition policy is applied by the Commission. Its purpose is to identify in a systematic way the competitive constraints faced by the undertakings involved. By defining a market in terms of both a *product* and *geographic* dimension, those actual competitors of the undertakings involved representing an effective competitive pressure capable of constraining their behaviour and of preventing them from behaving independently are identified.¹⁰⁸

¹⁰² See Chalmers, Hadjiemmanuil, Monti, Tomkins, pp. 1025-6.

¹⁰³ Middleton, p. 300.

¹⁰⁴ See Chalmers, Hadjiemmanuil, Monti, Tomkins, p. 1026.

¹⁰⁵ Commission *Notice on the Definition of the Relevant Market for the Purposes of Community Competition Law*, ([1997] OJ C 372).

¹⁰⁶ Chalmers, Hadjiemmanuil, Monti, Tomkins, pp. 1026-27 and p. 1035.

¹⁰⁷ See the *Discussion Paper*, para. 12.

¹⁰⁸ See the *Notice*, para. 2.

Naturally, the definition of the relevant market has a decisive influence on the assessment of a competition case.¹⁰⁹ The more narrowly the relevant market is defined, the more likely it is that the undertaking in question is deemed to be in a dominant position.¹¹⁰ Although it must be emphasised that market definitions do not always have clear limits and obviously should not alone determine whether the firm has market power, they do focus attention on the factors relevant to appraising market power.¹¹¹

Three principal sources of competitive constraints must be considered when defining the market. The first, *demand-side substitutability*, consists in identifying what the relevant *product* is from the perspective of consumers. The second requires determining, again from the consumer perspective, what the *relevant geographical market* is. Finally, *supply-side substitutability*, involves an inquiry into whether there are any *potential competitors* who might enter the relevant market in the future.¹¹²

From an economic perspective, demand-side substitution constitutes the most effective constraint on the suppliers of a given product. If customers are in a position to switch easily to available substitute products or to suppliers located elsewhere, an undertaking will not be able to exert a significant impact on the conditions of sale, such as prices. The task of defining the market is therefore concerned with identifying the effective alternative sources of supply for the customers of the relevant undertaking, both in terms of products/services and geographic location of suppliers.

By way of contrast, the constraints on firms arising from supply-side substitutability and potential competition are in general less immediate and in any event require an analysis of additional factors. As a result, these are taken into account at the assessment stage of competition analysis.¹¹³

(i) Product Market Definition & Demand-Side Substitution – The traditional approach to market definition is best illustrated by the *United Brands* case, where the ECJ was confronted with the question whether bananas represented a market of its own. In the Court's words, '[f]or the banana to be regarded as forming a market which is sufficiently differentiated from other fruit markets it must be possible for it to be singled out by such special features distinguishing it from other fruits that it is only to a limited extent interchangeable with them and is only exposed to their competition in a way that is hardly perceptible'.¹¹⁴

¹⁰⁹ See the Notice, para. 4.

¹¹⁰ Conversely, a too wide definition indicates a smaller market share and thus risks understating the firm's market power. The effect may be that an undertaking is (falsely) viewed as not in a dominant position, with the consequence that it falls outside of the ambit of Article 82 EC.

¹¹¹ V. Korah, '*EC Competition Law*', Hart Publishing Limited, 2001, p. 82.

¹¹² Chalmers, Hadjiemmanuil, Monti, Tomkins, p. 1026. Note that markets may also need to be defined in terms of time (*temporal markets*), e.g. where the market conditions considered are limited in time or operate on a seasonal basis. See Middleton, p. 314.

¹¹³ See the Notice, paras. 13-14.

¹¹⁴ Case 27/76 *United Brands Company and United Brands Continentaal BV v Commission of the European Communities*, [1978] ECR 207, para. 22.

Having pointed out that the banana was always available and that the question whether it could be replaced by other fruits therefore had to be determined over the whole of the year, the Court found that no significant long-term cross-elasticity existed.¹¹⁵ In particular however, the banana was found to have ‘certain characteristics, appearance, taste, softness seedlessness, easy handling, a constant level of production which enable it to satisfy the constant needs of an important section of the population consisting of the very young, the old and the sick’. From this followed that ‘a very large number of consumers having a constant need for bananas are not noticeably or even appreciably enticed away from the consumption of this product by the arrival of other fresh fruit on the market’. Consequently, the banana market was viewed to be a market which was sufficiently distinct from the other fresh fruit markets.¹¹⁶

The assessment of demand-side substitution thus entails a determination of the range of products, which are viewed as substitutes by the consumer. One way of determining this is by applying the so-called ‘*SSNIP-test*’ (*Small but Significant Non-transitory Increase in Price*), which ‘can be viewed as a speculative experiment, postulating a hypothetical small, lasting change in relative prices and evaluating the likely reactions of consumers to that increase’.¹¹⁷ The question posed in the test is ‘whether the parties’ customers would switch to readily available substitutes or to suppliers located elsewhere in response to a hypothetical small (in the range 5 to 10 per cent) but permanent relative price increase in the products and areas being considered. If substitution were enough to make the price increase unprofitable because of the resulting loss of sales, additional substitutes and areas are included in the relevant market. This would be done until the set of products and geographical areas is such that small, permanent increases in relative price would be profitable.’¹¹⁸ At that point, the ability to profitably raise prices by 5 to 10 per cent would signify that the products and areas in question constitute a market that is worth monopolizing.¹¹⁹

One problem with the SSNIP-test in the Article 82 context is, however, that the test assumes that the prevailing price constitutes the appropriate benchmark for the analysis. This is an assumption that generally does not hold in such cases. As the very notion of dominance involves an assessment of whether or not the undertaking in question is subject to effective competitive constraints, the appropriate benchmark for this assessment is the competitive price, which may not be the prevailing price.¹²⁰ Additional methods are thus required to ensure that the market has been correctly defined. These involve (i) reconstructing the competitive price to apply the SSNIP test, (ii) examining the characteristics and intended use of the products concerned to assess whether they are capable of satisfying the

¹¹⁵ Id. paras. 27-28.

¹¹⁶ Id. paras 34-35.

¹¹⁷ See the Notice, para. 15.

¹¹⁸ See the Notice, para. 17.

¹¹⁹ See the Discussion Paper, para. 14.

¹²⁰ Id. para. 15. See also Chalmers, Hadjiemmanuil, Monti, Tomkins, p. 1038.

inelastic consumer need and (iii) comparing prices across various regions to determine the geographic and product market.¹²¹

As to *product market definition in the pharmaceutical sector*, the Commission distinguishes between: (i) prescription pharmaceuticals, (ii) over the counter pharmaceuticals, and (iii) new products¹²². Each of these markets is then further segmented by therapeutic indications, i.e. degree of similarity in clinical effects.¹²³ To this end, the Commission uses the European Pharmaceutical Marketing Research Association's or the World Health Organisation's 'Anatomical Therapeutic Classification' (ATC), usually at level 3 of such classification.¹²⁴ However, the Commission has acknowledged that it may be appropriate to carry out an analysis at other levels of the ATC system, where using a level 3 category does not reflect the 'true' product market. Thus, a given ATC 3 class may therefore be subdivided into distinct market segments. Conversely, certain Commission decisions have held that the ATC 3 classification is too narrow to define the relevant product market and that several ATC classes may be included in the same product market.¹²⁵

(ii) Geographical Market definition – Once the product market is correctly defined it is necessary to identify the geographical extent of the market. According to the general rule, the geographical market is that territory where 'the objective conditions of competition applying to the product in question must be the same for all traders'.¹²⁶ Some markets will be necessarily localised, while others may be global.¹²⁷ Obviously, such a decision will have an impact on the level of competition on that market.

(iii) Supply-Side Substitution & Potential Competition – Finally, *supply-side substitution* is another constraint that may be taken into account when defining markets. It can be said to exist when 'suppliers are able to switch production to the relevant products and market them in the short term

¹²¹ Id. paras 16-19.

¹²² i.e. products that are not yet on the market but which are at an advanced stage of development, that is to say either at Phase II or Phase III of clinical trials.

¹²³ See, e.g. Commission Decisions M.1378, *Hoechst/Rhône-Poulenc*, January 30, 2004 and M.737, *Ciba-Geigy/Sandoz*, February 4, 1998.

¹²⁴ See, e.g. Commission Decisions M.3544, *Bayer Healthcare/Roche (OTC business)*, November 19, 2004; M.3354, *Sanofi-Synthelabo/Aventis*, April 26, 2004; and M.2922, *Pfizer/Pharmacia*, February 27, 2003.

¹²⁵ Gunther & Breuvert, pp. 680-81. Note that in the Commission's *AstraZeneca* decision, AZ's dominance arose at level 4 of the ATC system. This is the first Article 82 case in which this level has been used. See Sophie Lawrance, 'United Kingdom: Commission explains AstraZeneca decision', *Managing Intellectual Property*, September 2006, at <http://www.managingip.com/includes/magazine/PRINT.asp?SID=648513&ISS=22412&PUBID=34>. Visited on July 5, 2007.

¹²⁶ *United Brands*, para. 44.

¹²⁷ Conditions that affect the geographical extent of the market are e.g. transportation costs relative to the price of the product, national technical standards and national preferences. While these factors can be said to be of general application, others such as language and culture apply only to specific economic sectors such as the media sector, where markets tend to be national or regional. Chalmers, Hadjiemmanuil, Monti, Tomkins, p. 1030. See also Middleton, p. 313.

without incurring significant additional costs or risks in response to small and permanent changes in relative prices'. Where this is the case, the additional production that is put on the market will have a disciplinary effect on the behaviour of the companies involved, which in terms of effectiveness and immediacy will be equivalent to that of demand substitution.¹²⁸

However, since the conditions under which potential competition will actually represent an effective competitive constraint depend on the analysis of specific factors such as circumstances related to the conditions of entry, potential competition is generally not taken into account when defining markets. If required, this analysis is rather carried out at a subsequent stage, in general once the position of the companies involved in the relevant market has already been ascertained, and when such position gives rise to concerns from a competition point of view.¹²⁹

The Concept of Dominance – The leading definition of dominance was formulated by the ECJ in *United Brands*, where it stated that a 'dominant position [...] relates to a position of economic strength enjoyed by an undertaking which enables it to prevent effective competition being maintained on the relevant market by giving it the power to behave to an appreciable extent independently of its competitors, customers and ultimately of its consumers'. Moreover, the Court added that '[i]n general a dominant position derives from a combination of several factors which, taken separately, are not necessarily determinative'.¹³⁰

In line with the settled case law, the *Discussion Paper* also states that the definition of dominance consists of three components;¹³¹

- (i) There must be a *position of economic strength* on a market
- (ii) which *enables the undertaking(s) in question to prevent effective competition being maintained* on that market
- (iii) by affording it the *power to behave independently to an appreciable extent*.

The first component implies and confirms that dominance exists in relation to a market. Naturally, it cannot exist in the abstract. It also implies that an undertaking either on its own or together with other undertakings must hold a leading position on that market compared to its rivals.¹³²

The second and third components concern the link between the position of economic strength held by the undertaking concerned and the competitive process, in other words the way in which the undertaking and other players act and interact on the market. According to settled case law dominance is the ability to prevent effective competition being maintained on the market and to act to an appreciable extent independently of other players.¹³³

The special feature of dominance – the notion of independence – is related to the level of competitive constraint facing the undertaking(s) in question.

¹²⁸ Notice, para. 20.

¹²⁹ Id. para. 24.

¹³⁰ *United Brands*, paras. 65-66. The definition was confirmed in Case 322/81 *NV Nederlandsche Banden Industrie Michelin v Commission of the European Communities*, [1983] ECR 3461 para. 38.

¹³¹ See the Discussion Paper, para. 21 (emphasis added).

¹³² Id. para. 22.

¹³³ Id. para. 23.

Dominance can only exist where the undertaking concerned is not subject to effective competitive constraints, i.e., where it has substantial market power.¹³⁴ *Market power* is the power to influence market prices, output, innovation, the variety or quality of goods and services, or other parameters of competition on the market for a significant period of time.¹³⁵ The decisive factor is thus that the undertaking has the power to harm the competitive process, either by harming consumers or by harming competitors. Clearly, different degrees of such dominance may exist. While some undertakings are so powerful that they face no competitive constraint whatsoever, other dominant undertakings may face some competition, but are strong enough to hold smaller competitors back. Regardless of the degree however, the ECJ measures dominance by first considering the undertaking's *market share* and secondly, by *other factors* used to determine the undertakings position vis-à-vis its competitors, customers and consumers.¹³⁶

(i) Market Shares – Market shares, established by calculating the respective undertakings' shares of total sales in the relevant market, are used as a starting point and a preliminary filter to determine whether there is dominance.¹³⁷

As evidenced by *Hoffmann-La Roche*,¹³⁸ the ECJ puts great store in market shares as an indication of market strength. The larger the market share, the stronger an undertaking generally is in comparison to its competitors.¹³⁹ However, the ECJ has also recognized that their value in determining dominance varies depending on the market structure. Hence, the Court asks for more than a mere calculation of market shares. Not only should the undertaking hold the high market shares for some time, but its rivals' market shares should also be considerably smaller. Only in such a situation can the dominant firm be convinced that it has enough power to resist threats from competitors. In line with this reasoning, the Commission stated in *AKZO* that 'market share, while important, is only one of the indicators from which the existence of a dominant position may be inferred. Its significance in a particular case may vary from market to market according to the structure and characteristics of the market in question. To assess market power for the purposes of the case at hand, the Commission must consider also all the relevant economic evidence.'¹⁴⁰ The *Discussion Paper* confirms this approach by stressing that the strength of any indication based on market

¹³⁴ Id.

¹³⁵ Id. para. 24.

¹³⁶ *Michelin*, para. 31. See also Chalmers, Hadjiemmanuil, Monti, Tomkins, p. 1041.

¹³⁷ *Michelin* para. 29.

¹³⁸ Case 85/76 *Hoffmann-La Roche & Co. AG v Commission* [1979] ECR 461.

¹³⁹ The ECJ has suggested that undertakings with very high market shares (around 80 per cent) may be treated differently from those who are in a less strong position. Following *Irish Sugar plc v Commission*, [1999] ECR II-2969, it appears clear that the stronger the market position of an undertaking, the more strictly they will be controlled by Community competition law. See Middleton, pp. 317-20.

¹⁴⁰ 85/609/EEC: Commission Decision of 14 December 1985 relating to a proceeding under Article [82] of the EEC Treaty (IV/30.698 - *ECS/AKZO*), ([1985] OJ L 374/1, paras 68-69).

share depends on the facts of each individual case and that market share is only a proxy for market power, which is the decisive factor.¹⁴¹ Nevertheless, ‘rules of thumb’ have been formulated in the case law suggesting, amongst other things, that a market share of 50 per cent can give rise to a presumption of dominance.¹⁴² Such a presumption could, of course, be rebutted if the undertaking could adduce evidence to indicate that its apparent strength shown by its market share does not in reality give rise to dominance and true independence.¹⁴³ In many cases, however, dominant firms that have held market shares of over 50 per cent while their competitors have had considerably smaller market shares, have been unable to do so.¹⁴⁴ Even a market share between 40 and 50 per cent has been sufficient to identify a dominant position once other factors were taken into consideration, for instance where there were significant barriers to entry.¹⁴⁵

(ii) Other Factors: Barriers to/Ease of Entry – The most obvious objection to a monopolist is that he is in a position to reduce output and thereby increase the price of his products above the competitive level. However, if barriers to entry are absent or low, a monopolist earning monopoly profits would be expected to attract new entrants to the market – exploitation of a monopoly position may thus actually increase competition.¹⁴⁶ In the *Discussion Paper*, barriers to entry are defined as ‘factors that make entry impossible or unprofitable while permitting established undertakings to charge prices above competitive level.’¹⁴⁷ When identifying possible barriers to expansion and entry it is therefore important to focus on whether rivals can reasonably replicate circumstances that give advantages to the allegedly dominant undertaking. According to the Commission, barriers to expansion and entry can have a number of origins relating to the legal or economic environment on the relevant market, so that absolute cost-advantages, including access to innovation, R&D and IP also may be considered as barriers.¹⁴⁸ This follows the reasoning of the ECJ in cases where a dominant position has been held to be protected by ownership of IPRs which prevent others from duplicating the dominant undertaking’s

¹⁴¹ See the *Discussion Paper*, para. 32.

¹⁴² Case 62/86 *AKZO v Commission* [1991] ECR I-3359, para. 60.

¹⁴³ A number of reasons why apparent market strength may not lead to dominance may exist, one of which is the absence of barriers to entry. See Middleton, p. 317.

¹⁴⁴ E.g. Case 322/81 *Nederlandsche Banden-Industrie Michelin NV v Commission* [1983] ECR 3461 (dominant firm with a market share of approximately 57-60 per cent and the others with market shares between 4 and 8 per cent).

¹⁴⁵ *United Brands*, paras. 109-10; Case T-219/99 *British Airways v Commission* [2003] ECR II-5917, paras. 211-24. See Chalmers, Hadjiemmanuil, Monti, Tomkins, pp. 1042-3.

¹⁴⁶ Whish, p. 194. See also the *Discussion Paper*, para. 34, stating that where barriers to expansion and entry are low, the fact that one undertaking has a high market share may not necessarily point to dominance, since any attempt by an undertaking to increase prices above the competitive level would attract expansion or new entry by rivals with the effect that the price increase would be undermined.

¹⁴⁷ See the *Discussion Paper* para. 38.

¹⁴⁸ *Id.* para. 40.

products.¹⁴⁹ Patents and the protection they afford may thus be seen to represent effective legal barriers to entry.

One criticism that has been raised in this context is that by considering these factors one is merely using the efficiencies of the dominant firm as a means to determine dominance. That criticism was rejected by the ECJ in *Michelin* where the Court took the opportunity to point out that ‘a finding that an undertaking has a dominant position is not in itself a recrimination but simply means that, irrespective of the reasons for which it has such a dominant position, the undertaking concerned has a *special responsibility* not to allow its conduct to impair genuine undistorted competition on the common market.’¹⁵⁰ However, that reasoning does not seem to have convinced those who think that a too wide definition of dominance, combined with the ‘special responsibility’, places a too heavy burden on dominant undertakings, whose commercial freedom is adversely affected, paradoxically restricting the very kind of competition they are said to endanger.¹⁵¹

(iii) Other Factors: Buyer power – Buyer power is another factor that can serve to counter a finding of dominance. According to the *Discussion Paper*, the market position of buyers provides an indication of the extent to which they are likely to constrain the allegedly dominant undertaking. However, the presence of strong buyers can only serve to counter a finding of dominance if it is likely that in response to prices being increased above the competitive level, the buyers in question will pave the way for effective new entry or lead existing suppliers in the market to significantly expand their output so as to defeat the price increase. In other words, the strong buyers should not only protect themselves, but effectively protect the market.¹⁵²

To be able to do this, the demand side will generally have to be highly concentrated, which is more of an exception than a norm in most industries. One such exception however, is represented by the pharmaceutical sector, where single buyers such as national health authorities, or a few powerful purchasers such as clinics or hospitals, frequently constitute a highly concentrated demand side which has sufficient leverage against the suppliers to affect price.¹⁵³

(iv) Other Factors: Conduct – Though not mentioned in the *Discussion Paper*, and though it may seem methodologically problematic, the case law of the ECJ can be seen to contain yet another category. Since a dominant position requires that the undertaking is able to act in a certain way, the conduct of the undertaking on the relevant market has also occasionally

¹⁴⁹ E.g. Case 22/78 *Hugin Kassaregister AB v Commission* [1979] ECR 1869; Case T-30/89 *Hilti v Commission* [1991] ECR II-1439 (affirmed in Case C-53/92 P *Hilti v Commission* [1994] ECR I-667).

¹⁵⁰ *Michelin*, para. 57 (emphasis added).

¹⁵¹ See Chalmers, Hadjiemmanuil, Monti, Tomkins, pp. 1045-46.

¹⁵² See the *Discussion Paper*, para. 41.

¹⁵³ EFPIA paper ‘Article 82 EC: Can It Be Applied to Control Sales by Pharmaceutical Manufacturers to Wholesalers?’ page 41. Available at http://www.efpia.org/6_publ/Article82ECNov04.pdf. Visited on the April 23 2007.

been considered when examining whether it is dominant. In other words, the fact that the undertaking has acted in an abusive way may be viewed as a factor indicating dominance.¹⁵⁴

To summarize the preceding section, any finding of a *dominant position* or *market power* must consider the actual circumstances of each particular case. First, defining the *relevant product and geographic markets* must take into account possible substitutes on the demand side, supply side and potential competition. Only where the relevant market has been correctly defined can a high market share be said to be truly indicative of dominance. Second, despite the fact that high *market shares* could constitute an indicator of market power, *other factors* such as low barriers of entry or buyer power could counter a finding of dominance and must always be made subject of a thorough analysis.

4.1.1.2 Abuse

Once it has been decided that a firm has a dominant position in a substantial part of the common market, it is necessary to consider what constitutes an abuse of that position. As Article 82 of the EC Treaty does not forbid the holding of a dominant position *per se* but only the abuse of it, the meaning of abuse is of vital importance. Although the term is not defined, Article 82 sets out an illustrative list of abusive practices. The list however, ‘merely gives examples, i.e., is not an exhaustive list of the kinds of abusive exploitation of a dominant position prohibited by the Treaty’,¹⁵⁵ and the Commission decisions and the case law of the Community Courts have revealed Article 82 to be a formidable weapon.¹⁵⁶

In *Hoffman-La Roche*, the ECJ held that: ‘the concept of *abuse is an objective concept* relating to the behavior of an undertaking in a dominant position which is such as to influence the structure of a market where, as a result of the very presence of the undertaking in question, the degree of competition is weakened and which, through recourse to methods different from those which condition *normal competition* in products or services on the basis of the transactions of commercial operators, has the effect of hindering the maintenance of the degree of competition still existing in the market or the growth of that competition.’¹⁵⁷

The often cited reference to the concept of abuse as an ‘objective’ one, means that behaviour can be abusive even where the dominant firm had no intention of infringing Article 82 EC. The fact that there are certain abuses where evidence of intention is an integral part of establishing an infringement does not contradict this idea. As conduct may be harmful to

¹⁵⁴ See Eilmansberger in Streinz, ‘EUV/EGV-Kommentar’, C.H. Beck 2003, p. 1017.

Compare the *AstraZeneca* decision.

¹⁵⁵ Case 6/72 *Continental Can v Commission* [1973] ECR 215, Cases C-395/96 *P etc Compagnie Maritime Belge Transport SA v Commission* [2000] ECR I-1365.

¹⁵⁶ See Jones & Sufrin, p. 239; Whish, p. 194; Middleton, p. 297; See also Chalmers, Hadjiemmanuil, Monti, Tomkins, pp. 1025-6. The Commission and Courts have often been accused of pushing the boundaries of the provision, e.g. in the *AstraZeneca* decision below.

¹⁵⁷ *Hoffmann-La Roche*, para. 91 (emphasis added).

the market whether it was intended to be harmful or not, intention is not a key component of the concept of abuse.¹⁵⁸

The reference to 'normal' competition in this context may seem questionable. In fact, many of the practices that have been condemned under Article 82 cannot be said to be abnormal. Rather, their use by undertakings which were already in a position of some strength has had an impact that has drawn the attention of the Commission.¹⁵⁹

As was touched on above, whilst it is not an offence for a firm to have a dominant position, a firm in a dominant position has a 'special responsibility' not to allow its conduct to impair undistorted competition on the common market,¹⁶⁰ and it appears that this responsibility becomes greater (so that a finding of abuse becomes more likely) where the firm under investigation is not merely dominant, but 'super-dominant'.¹⁶¹

Regarding the kind of behaviour that falls within the mischief of Article 82, *exploitative* and *exclusionary* (anti-competitive) abuses have generally been considered separately.¹⁶² This was also the approach taken by the Commission in the recent *Discussion Paper*, which only comments on exclusionary abuses.

According to the *Discussion Paper*, the essential objective of Article 82 EC when analyzing exclusionary conduct is the protection of competition on the market as a means of enhancing consumer welfare and of ensuring an efficient allocation of resources. The concern is to prevent exclusionary conduct of the dominant firm which is likely to limit the remaining competitive constraints on the dominant company, including entry of newcomers, so as to avoid that consumers are harmed. Consequently, it is competition, and not competitors as such, that is to be protected. Furthermore, the purpose of Article 82 EC is not to protect competitors from dominant firms' genuine competition based on factors such as higher quality, novel products, opportune innovation or otherwise better performance, but to ensure that these competitors are also able to expand in or enter the market and compete therein on the merits, without facing competition conditions which are distorted or impaired by the dominant firm.¹⁶³ Certain exclusionary conduct which is clearly not competition on the merits – in particular conduct which clearly creates no efficiencies and which only raises obstacles to residual competition – will be presumed to be an abuse.¹⁶⁴ Such a presumption will be rebuttable by a dominant company which is able to provide convincing evidence that the conduct does not and will not have the alleged likely exclusionary effect, or that the conduct is objectively justified.¹⁶⁵

¹⁵⁸ Jones & Sufrin, p. 250.

¹⁵⁹ Mark Furse, '*Competition Law of the UK and EC*', Blackstone Press 1999, p. 202.

¹⁶⁰ See *Michelin*, para. 57.

¹⁶¹ See Whish, p. 194 and Middleton, pp. 319-20.

¹⁶² Chalmers, Hadjiemmanuil, Monti, Tomkins, p. 1048.

¹⁶³ See the *Discussion Paper*, para. 54.

¹⁶⁴ When defining the presumption of abuse as 'conduct clearly not competition on the merits', the *Discussion Paper* makes a single but important reference to the *AstraZeneca* decision. The final outcome of this case is bound to have a significant impact on the future interpretation of the concept of exclusionary abuses.

¹⁶⁵ *Id.* para. 60. Compare Whish, pp. 194-95.

4.1.1.3 Effect on Trade

Due to the particular features of Article 82 EC and its focus on the protection of the development of the Single Market, there is great focus on the structure of markets. Article 82 only applies to conduct that affects trade between Member States. However, Article 82 may apply to conduct that only occurs within one Member State, if that conduct has the potential effect of retarding the development of intra-Community trade.¹⁶⁶

4.1.1.4 Absence of Defence

In view of the aim to adopt a more economic approach to antitrust enforcement, the *Discussion Paper* comments on both *objective justifications* and *efficiencies* as possible defences to abuse.¹⁶⁷ According to the Commission, exclusionary conduct may escape the prohibition of Article 82 in case the dominant undertaking can provide an objective justification for its behaviour or it can demonstrate that its conduct produces efficiencies, which outweigh the negative effect on competition.¹⁶⁸

Two types of possible objective justifications are mentioned: (i) The first type – the ‘objective necessity defence’ – is where the dominant company is able to show that the otherwise abusive conduct is actually necessary conduct on the basis of objective factors external to the parties involved and in particular external to the dominant company. (ii) The second type – ‘meeting competition defence’ – is where the dominant company is able to show that the otherwise abusive conduct is actually a loss minimising reaction to competition from others.¹⁶⁹

In relation to the efficiency defence the *Discussion Paper* states that ‘the dominant company must be able to show that the efficiencies brought about by the conduct concerned outweigh the likely negative effects on competition resulting from the conduct and therewith the likely harm to consumers that the conduct might otherwise have’.¹⁷⁰

4.1.2 National IPRs, the EC Treaty & Article 82

As noted above, IPRs in the EC constitute legal rights granted by national law, which give the holder an exclusionary (sometimes exclusive) right to the exploitation of an emanation of the intellect. As such, they are of vital importance to the economic wellbeing of the Community. Surprising as it may seem for a document claiming to lay down the foundations for the single market, the EC Treaty itself only touches on IP. The general rule about IPRs is contained in Article 295, which stipulates: ‘This treaty shall in no way prejudice the rules in Member States governing the system of property ownership.’ By recognising the existence and ownership of rights given by national law, the provision also excludes Community legislative

¹⁶⁶ See Middleton, pp. 298-99.

¹⁶⁷ See the Discussion Paper, Section 5.5 – *Possible Defences: Objective Justifications and Efficiencies*, pp. 24-28.

¹⁶⁸ See the Discussion Paper, para. 77.

¹⁶⁹ See the Discussion Paper, para.78.

¹⁷⁰ See the Discussion Paper, p. 79.

competence in the IP area. As a general rule, the regulation of the exploitation and acquisition of IPRs thus takes place on a national level. However, to a certain extent, this is modified by the EC rules on free movement of goods and competition (i.e. Articles 28-30 and 81-82 respectively).¹⁷¹

As regards *the IP-free movement relationship*, there is a fundamental conflict between the recognition of national IPRs and the basic principle of the free movement of goods, contained in Article 28 EC.¹⁷² For if goods cannot be imported freely because it would infringe a national patent, or if such a patent is used to prevent parallel import, the market is clearly divided along national lines. In other words, the free circulation of goods may be seriously impeded by national IPRs. A derogation from the free movement provision in Article 28 is provided in Article 30, which also is the only part of the Treaty that specifically deals with IPRs. Under this article, ‘Article 28 [...] shall not preclude prohibitions or restrictions on imports [...] justified on grounds of [...] the protection of industrial and commercial property.’¹⁷³ This implies that Community law accepts that restrictions on free movement may be justified to protect national IPRs. However, Article 30 contains a final condition in the last sentence. The restrictions must not constitute ‘a means of arbitrary discrimination or a disguised restriction’ on inter-Member State trade. Arguably, this can be described as the ‘sting in the tail’,¹⁷⁴ which has been used to justify many of the limitations which the ECJ has placed on the exercise of national IPRs.¹⁷⁵

Furthermore, that the regulation of IPRs is a matter of national concern and that national IP rules are accepted and protected by the Treaty has not prevented Community interference where national IPRs hinder *competition* on the internal market.¹⁷⁶ Put differently, the national IP rights and rules must be exploited and applied in accordance with the Treaty rules on competition contained in Articles 81 and 82 EC. As far as the latter provision is concerned, there are two facets to *the relationship between Article 82 and IPRs*: (i) First, there is the extent to which the ownership of IPRs puts the holder in a *dominant position*. (ii) Secondly, there is the question whether the holding, acquisition, or exploitation of IPRs can constitute an *abuse* of a dominant position, and if so in what circumstances.

¹⁷¹ See Jones & Sufrin, pp. 560-61.

¹⁷² Under this article ‘[q]uantitative restrictions on imports and all measures having equivalent effect shall, without prejudice to the following provisions, be prohibited between the Member States.’

¹⁷³ Note that ‘Intellectual Property’ is the generic phrase now used both at Community and international level. See Case 78/70, *Deutsche Grammophon v. Metro* [1971] ECR 487 and Cases 55 & 57, *Musik-Vertrieb Membran v. GEMA* [1981] ECR 147.

¹⁷⁴ V. Korah, ‘*An Introductory Guide to EC Competition Law and Practice*’, 7th edn. Hart Publishing, Oxford, 2000, 259 in Jones & Sufrin, p. 561.

¹⁷⁵ See Jones & Sufrin, pp. 560-61.

¹⁷⁶ In Case 15/74, *Centrafarm BV v. Sterling Drug* [1974] ECR 1147, the ECJ stated that, in the absence of a harmonisation of the rules relating to IPRs, the discrepancy between existing national IP laws can create obstacles to the free movement of goods as well as to competition in the internal market.

In relation to the first facet, the ECJ has consistently held that the ownership of IPRs does not necessarily mean that the owner has a dominant position.¹⁷⁷ The legal monopoly may not necessarily amount to an economic monopoly if the relevant market is wider than the protected product. However, the fact that access to a market is protected by IPRs will serve as a barrier to entry and may thus be relevant as a factor indicating dominance. This was the case in *Hugin, Hilti and Tetra Pak II*.¹⁷⁸

In relation to the second facet, although Community law (as will be seen below) in the absence of harmonisation measures does not regulate the conditions upon which national law grants IPRs (i.e. their *existence*),¹⁷⁹ it may curtail the *exercise* of them where this can be characterised as abusive.¹⁸⁰ Moreover, under ‘exceptional circumstances’ and where a particular exercise of IPRs conflicts with Article 82 EC, a compulsory licence may be ordered.¹⁸¹ However, reconciling the exploitation of IPRs with the concept of abuse is bound to always be problematic and controversial. For even where abuse is defined as conduct, which goes beyond normal competition and affects the structure of competition on already dominated markets, there is the difficulty, if not impossibility, of distinguishing such conduct from the normal exploitation of IPRs.¹⁸²

4.2 Antitrust Law in the US

The starting point for all competition laws may be traced to US antitrust. The *Sherman Act 1890* is the earliest example of a ‘modern’ competition law system and remains in force today.¹⁸³ Although the Sherman Act has

¹⁷⁷ Case 24/67 *Parke Davis v. Probel* [1968] ECR 55; Cases C-241-241/81 *P, RTE & ITP v. Commission (Magill)* [1995] ECR I-743. See also the Commission ‘Notice providing guidelines on the application of Article 81 of the EC Treaty to technology transfer agreements’, 2004 OJ (C 101) 2, paras. 16-17. See also the Discussion Paper, para. 40.

¹⁷⁸ Case 22/78, *Hugin Kassaregister AB and Hugin Cash Registers Ltd. v. European Commission* [1979] ECR 1869, *Eurofix-Bauco/Hilti* [1998] OJ L65/19, Case C-333/94P, *Tetra Pak International SA v. Commission* [1996] ECR I-5951.

The basic principle is that ‘so far as a dominant position is concerned, it is to be remembered at the outset that the mere ownership of an IPR cannot confer such a position’. There is a difference between a legal and an economic monopoly. The latter depends on whether the product protected by the IPR is co-extensive with a ‘relevant market’ in the competition sense. If the protected product is part of a wider market the IPR will not in itself create dominance, but if the market is narrowed to comprise only the product covered by the IPR then there will be a de facto monopoly, because the IPR will constitute a barrier to entry preventing supply substitution or new entrants coming onto the market. The ECJ and the Commission have often defined very narrow markets, and in some cases the narrow market so defined has been completely covered by an undertaking’s IPRs. This leads inevitably to a finding of dominance. See Jones & Sufrin, p. 309. Compare the *AstraZeneca* decision.

¹⁷⁹ See e.g. Case 144/81, *Keurkoop v. Nancy Kean Gifts* [1982] ECR 2653; Cases C241-241/81P, *RTE & ITP v. Commission* [1995] ECR I-743, para. 49.

¹⁸⁰ See below.

¹⁸¹ See below.

¹⁸² See Jones & Sufrin pp. 622-628.

¹⁸³ ‘An Act to protect trade and commerce against unlawful restraints and monopolies’, 15 USC, 2 July 1890. It was supplemented by later statutes, the *Clayton Act* (1914), the

been supplemented by other legislation over the last century, the Act remains central to antitrust policy in the United States. The Supreme Court has even described the antitrust laws as the ‘Magna Carta of the free enterprise’ and compared them to the Bill of Rights.¹⁸⁴ Moreover, the influence of US antitrust scholars on the development of competition laws throughout the world has been profound.¹⁸⁵

The three main statutory provisions defining conduct that is unlawful under the US antitrust laws are Sections 1 and 2 of the Sherman Antitrust Act¹⁸⁶ and Section 7 of the Clayton Act.¹⁸⁷ In addition, there are other statutory antitrust provisions that occasionally come into play in the IP context, such as Section 5 of the FTC Act¹⁸⁸ and Section 3 of the Clayton Act.¹⁸⁹

Whereas Section 1 of the Sherman Act prohibits ‘every contract, combination [...] or conspiracy’ at federal level that constitutes an ‘unreasonable’ restraint of trade,¹⁹⁰ Section 2 – the American equivalent to Article 82 EC – targets unilateral conduct and condemns ‘monopolization’.

4.2.1 S. 2 of the Sherman Act – Monopolization

Section 2, forbidding the use of monopoly power ‘to foreclose competition, to gain a competitive advantage, or to destroy a competitor’,¹⁹¹ states:

‘Every person who shall monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among several States, or with foreign nations, shall be deemed guilty of a felony.’

Section 2, which reaches both collective conduct (combination or conspiracy) and unilateral conduct (monopolization and attempts to monopolize), thus has two elements:

- (i) the possession of *monopoly power* in the relevant market, and
- (ii) the *wilful acquisition or maintenance* of that power.¹⁹²

Due to the fact that the terms used are not capable of narrow definition and application, the courts have been given a relatively wide margin of appreciation in defining and applying them to the facts of each particular case. For many years, the uncertain scope of the laws was somewhat

Federal Trade Commission Act (1914), and the *Robinson-Patman Act* (1936). See Jones & Sufin, p. 18.

¹⁸⁴ *US v. Topco Associates*, 405 U.S. 596 (1972).

¹⁸⁵ See Middleton, pp. 13-14.

¹⁸⁶ 15 U.S.C. §§ 1, 2.

¹⁸⁷ *Id.* § 18. *Section 7 of the Clayton Act* prohibits certain stock and asset acquisitions where ‘the effect of such acquisition may be substantially to lessen competition, or to tend to create a monopoly.’ See Balto & Wolman, p. 15.

¹⁸⁸ *Id.* § 45. *Section 5 of the FTC Act* prohibits unfair methods of competition.

¹⁸⁹ *Id.* § 14. *Section 3 of the Clayton Act* prohibits certain forms of tying and exclusive dealing.

¹⁹⁰ *Standard Oil Co. of new Jersey v United States* (1911) 221 US 1.

¹⁹¹ *Eastman Kodak Co. v. Image Technical Servs., Inc.*, 504 U.S. 451, 482-83 (1992) (Kodak I) quoting *U.S. v. Griffith*, 334 U.S. 100, 107 (1948).

¹⁹² See Balto & Wolman, pp. 17-18.

curtailed by the use by the courts of *per se prohibitions* for various types of conduct considered presumptively anticompetitive. However, over the past twenty-five years *per se* prohibitions have in many areas given way to a more nuanced *rule of reason analysis* that takes the likely economic consequences of a particular course of conduct into account.¹⁹³ The basic focus of the antitrust inquiry is therefore to determine whether the conduct under scrutiny is likely to harm consumers. This leads to the inquiry of whether the conduct will serve to create or maintain monopoly power, or facilitate cartel behaviour so that monopoly power can be exercised jointly. As a rule of thumb, highly competitive markets where firms have low market shares or where it would be easy for new entrants to compete do not attract much antitrust concern. Conversely, restrictive conduct in highly concentrated markets with few competitors and high barriers to new entry is more likely to threaten the operation of competitive markets and is, therefore, closely scrutinized by the courts and antitrust agencies.¹⁹⁴

4.2.1.1 Monopoly Power in the Relevant Market

Monopoly power is defined as ‘the power to control prices or exclude competition.’¹⁹⁵ It may be ‘inferred from a firm's possession of a dominant share of a relevant market that is protected by entry barriers.’¹⁹⁶

To determine whether monopoly power exists in a *relevant market*, it is necessary to define the relevant product and geographic market. ‘Defining the relevant market is an indispensable element of any monopolization or attempt case.’¹⁹⁷ Whereas the *geographic market* is the geographic area to which customers may look for such competing products, the *product market* includes substitute products to which a customer may turn in response to a rise in price of the main product.¹⁹⁸ Thus, commodities that are ‘reasonably interchangeable’ make up part of the same relevant market.¹⁹⁹

As regards *the product market definition in the pharmaceutical sector*, the FTC's approach to market definition in this industry is arguably not as transparent as that of the European Commission.²⁰⁰ The overall impression is that the FTC's approach is one of considerable flexibility and pragmatism, based loosely on principles of substitutability and the SSNIP test²⁰¹. In non-

¹⁹³ This ‘rule of reason’ is at the heart of American law, and there is an ongoing and intense debate as to the place of such a rule in EC law. See Furse, p. 5.

¹⁹⁴ See Balto & Wolman, pp. 20-22.

¹⁹⁵ *U.S. v. E.I. Du Pont de Nemours & Co.*, 351 U.S. 377, 391 (1956).

¹⁹⁶ *U.S. v. Microsoft Corp.*, 253 F.3d 34, 51 (D.C. Cir. 2001).

¹⁹⁷ *Intergraph Corp. v. Intel Corp.*, 195 F.3d 1346, 1355 (Fed. Cir. 1999) For relevant market definitions, see generally US DoJ and FTC ‘*Horizontal Merger Guidelines*’ (April 2, 1992), § 1. Available at http://www.usdoj.gov/atr/public/guidelines/horiz_book/toc.html. Visited on June 20, 2007.

¹⁹⁸ *Grinnell Corp.*, 384 U.S. at 571.

¹⁹⁹ *E.I. Du Pont*, 351 U.S. at 395. See Balto & Wolman, p. 18.

²⁰⁰ See M. Howard Morse, ‘*Product market definition in the pharmaceutical industry*’ (2003) 71 *Antitrust Law Journal* 633.

²⁰¹ As defined by the Merger Guidelines, § 1.11, the SSNIP test consists in examining whether a ‘small but significant and nontransitory’ price increase would cause enough

merger cases, the FTC generally alleges narrow markets, limited to a single drug and its generic equivalent,²⁰² or, in a very limited number of cases, to generic drugs excluding the bio-equivalent brand name drug.²⁰³

Unfortunately, however, the FTC complaints are not particularly detailed and generally contain only market allegations without further discussion. The *Biovail* case is an illustrating example of this. Here, the FTC alleged a market for ‘Tiazac and generic bio-equivalent versions of Tiazac’ and asserted, without further evidence, (i) that even if other therapeutic agents could be used to treat hypertension and angina, including other branded and generic formulations of once-a-day diltiazem, those drugs ‘do not significantly constrain Tiazac’s pricing’ and (ii) that entry of a generic version of Tiazac ‘likely would result in a significant, immediate decrease in the sales of branded Tiazac and lead to a significant reduction in the average market price paid for Tiazac and its generic bioequivalents’.²⁰⁴

Furthermore, most of the antitrust cases involving pharmaceuticals end with settlement between the FTC and the undertakings concerned prior to judicial consideration. This leads to a scarcity of court decisions in these cases, with the consequence that it is not possible to know whether the market definitions made by the FTC would have been upheld. While the approach taken by the FTC may be justifiable on the basis of the SSNIP test, it seems that pragmatism is the driving force behind the FTC’s market definition in this context, as opposed to the seemingly more rigid (but more certain) focus by the Commission on ATC 3 classes.²⁰⁵

buyers to shift to other products so that the increase would be unprofitable for a hypothetical monopolist.

²⁰² See, e.g. *Abbott Labs. & Geneva Pharm., Inc.*, FTC Docket Nos C-3945, 3946 (May 22, 2000) (Complaint § § 10-12), available at www.ftc.gov/os/2000/05/c3945complaint.htm; *Hoechst Marion Roussel, Inc. & Andrx Corp.*, FTC Docket No.9293 (March 16, 2000) (Complaint § 12), available at <http://ftc.gov/os/2000/03/hoechstandrxycomplaint.htm>. Visited on June 20, 2007. Compare the *AstraZeneca* decision.

²⁰³ In recent merger enforcement actions, the FTC has alleged prescription drug markets ranging from those based upon a particular chemical compound, to broader markets based upon various drugs that have the same mechanism of action, to still broader markets of all drugs used to treat a particular disease or condition. It has also often included in the market not only marketed drugs, but other drugs under development, alleging ‘innovation markets’. See Gunther & Breuvert, pp. 680-81.

²⁰⁴ In *Biovail*, the Commission charged Biovail Corporation with illegally acquiring an exclusive patent license for the pharmaceutical Tiazac. The complaint further alleged that Biovail, in an effort to maintain its monopoly, wrongfully listed the acquired license in the US Food and Drug Administration’s ‘Orange Book’ for the purpose of blocking generic competition to its branded Tiazac. The consent order (Final Order October 2, 2002) required Biovail to divest part of its exclusive rights to DOV; prohibited the firm from taking any action that would trigger additional statutory stays on final FDA approval of a generic form of Tiazac; and also prohibited Biovail from wrongfully listing any patents in the Orange Book for a product for which the company already has an New Drug Application (NDA) from the FDA. See ‘*ABA Antitrust Section Spring Meeting, Summary of Bureau of Competition Activity, Fiscal Year 2002 Trough March 15 2006*’, p.25, available at <http://www.ftc.gov/reports/aba/abaspring2006.pdf>. Visited on June 20, 2007.

²⁰⁵ Gunther & Breuvert, pp. 680-81.

4.2.1.2 Wilful Acquisition or Maintenance of that Power

As it is possible to argue that it is the legitimate goal of any businessman to ‘monopolise’ his industry, a distinction has been drawn between the ‘wilful’ acquisition or maintenance of that power, which is condemned, and monopoly arising from better commercial practices (i.e. from growth or development as a consequence of a superior product, business acumen, or historic accident), which escapes the Act’s application.²⁰⁶

4.2.1.3 Attempted Monopolization

Attempted monopolization also infringes Section 2 of the Sherman Act. This requires a showing of:²⁰⁷

- (i) *intent to monopolize* a relevant market,
- (ii) *predatory conduct* in pursuit of that end,
- (iii) *a dangerous probability of success*, and
- (iv) *causal antitrust injury*.

4.2.2 IPRs, the Constitution & Section 2

Just as in the EC, there are two facets to the relationship between Section 2 of the Sherman Act and IPRs:

- (i) First, there is the extent to which the ownership of IPRs means that the holder possesses *monopoly power* in the relevant market.
- (ii) Secondly, there is the question whether the holding, acquisition, or exploitation of IPRs can constitute *wilful acquisition or maintenance* of such power, and if so, in what circumstances.

In relation to the first facet, US antitrust agencies concur with their EC counterparts that market power cannot be inferred from the ownership of IPRs alone.²⁰⁸ In particular, there is no economic basis for inferring market power from the mere fact that the defendant holds a patent.²⁰⁹ Yet, under

²⁰⁶ *U.S. v. Grinnell Corp.*, 384 U.S. 563, 570 (1966). See Balto & Wolman, p. 18; Furse, pp. 5-6.

²⁰⁷ *Transamerica Computer Co. v. IBM Corp.*, 698 F.2d 1377, 1382 (9th Cir. 1983). See Balto & Wolman, p. 18.

²⁰⁸ See the DoJ and FTC ‘*Antitrust Guidelines for the Licensing of Intellectual Property*’ (April 6, 1995), available at <http://www.usdoj.gov/atr/public/guidelines/0558.pdf>, para. 2.2 (visited on June 20, 2007). Compare the *EC Guidelines on technology transfer agreements*, paras. 16-17. See also the *EC Discussion Paper*, para. 40. See Czapracka, pp. 6-8.

²⁰⁹ As stated above, this is because there is a difference between the exclusive rights granted by IPRs and the monopoly power that is the concern of antitrust law. Exclusive rights in the patent will give rise to market power only if there are no substitutes to the patented product and provided that there is sufficient consumer demand for the product in question. Similarly, the fact that the owner of an IPR may be able to charge a price higher than the marginal cost does not mean that she enjoys monopoly power, as there is usually a high sunk cost involved in the development of a new product. In *Illinois Tool Works Inc. v. Independent Ink, Inc.*, 126 St. Ct. 1281 (U.S. 2006), the Supreme Court held that the fact that a tying product is patented does not support the presumption of market power in a patented product. See Czapracka, pp. 6-8; See also Eccles & Ferla, p. 5 and the *IP Guidelines*.

certain circumstances, IPRs may create barriers to entry and thus enhance market power.²¹⁰ Whether or not monopoly power is inferred from IPRs, the key issue is the definition of a relevant market. If the relevant market is defined narrowly so that it includes solely the product covered by an IPR, the IP holder will always be dominant.²¹¹ This was the case for example in *Eastman Kodak*, where the Supreme Court found that a single brand of product or service can be relevant market under the Sherman Act prohibition against monopolization.²¹²

As to the second facet, the question whether the holding, acquisition, or exploitation of IPRs can constitute an antitrust offence raises just as much controversy as in the EC. Whereas, in the US, the exclusive rights deriving from patents find their anchor in the US Constitution, the main antitrust principles are laid down in the Sherman Act which, if not formally part of the US Constitution, is of quasi-Constitutional force. Therefore, while it is beyond discussion that the US antitrust laws should be applied in such a way so as not to harm the IPRs duly recognized by the US Constitution, it is obvious as well that the acquisition and exploitation of patents are subject to the antitrust laws just like any other property.²¹³ As a result of this compromise, the exercise of patent rights may be restricted by the so called 'patent misuse doctrine'.²¹⁴ Moreover, despite the general rule that a US patent does not have to be licensed,²¹⁵ Section 2 may prohibit a firm from unilaterally refusing to license their IPRs where such a refusal would allow the firm to obtain or maintain monopoly power by excluding competition in a way that does not benefit consumers.²¹⁶ These issues will be returned to below.

²¹⁰ In the US, barriers to entry are generally defined as factors that allow incumbent companies earn supra-competitive returns without attracting entry. A patent, for example, may be a barrier to entry if it controls the only available technology. Czapracka, pp. 6-8.

²¹¹ Arguably, this may be justified e.g. in some cases concerning pharmaceuticals where there are no substitutes available to a patented medicine. See in general M. Howard Morse 'Product Market Definition in the Pharmaceutical Industry' 71 *Antitrust L.J.* 633 (2003).

²¹² *Eastman Kodak Co. v. Image Technical Services, Inc.* 504 U.S. 451, 481-482 (U.S. 1992). Compare *Magill*, (Case T-69/89, *RTE v. Commission*, 1991 ECR II-485, upheld on appeal by the ECJ in joined cases C-241/91 P and C-242/91 P, *RTE and ITP v. Commission*, 1995 ECR I-743) where the ECJ rejected the possibility that dominance could be inferred from possession of copyright, but accepted a very narrow definition of the market, basically coinciding with the copyrighted subject matter.

²¹³ Jacques Werner, *Antitrust and Intellectual Property: The Uneasy Relationship*, *The Journal of World Intellectual Property*, 1999 2(3), 417-422, at 421.

²¹⁴ Czapracka, p. 23.

²¹⁵ *Continental Paper Bag Co. v. E. Paper Bag Co.*, 210 U.S. 405, 429 (1908); 35 U.S.C. § 271(d)(4). This rule conforms to the fundamental principle of antitrust law that companies are allowed to unilaterally choose with whom they want to conduct business, see *U.S. v. Colgate & Co.*, 250 U.S. 300, 307 (1919).

²¹⁶ *Kodak I*, 504 U.S. at 480, n. 29 (1992). The court stated that a patent holder could refuse to license, but such refusal was subject to a rebuttable presumption that refusing to license was harmful to consumers. See also e.g. *Image Technical Serv., v. Eastman Kodak Co.*, 125 F.3d 1195, 1218 (9th Cir. 1997) (*Kodak II*). *CSU, L.L.C. v. Xerox Corp.*, 203 F.3d 1322, 1326 (Fed. Cir. 2000). See Balto & Wolman, pp. 44-45.

5 Antitrust Intervention

In the following, a closer look will be had at the main instances in which antitrust intervention in the IP context is thought to be justified in the EC and US systems.

5.1 The EC Approach

In its attempt to reconcile the conflicting demands of the economic integration of the single market with the protection of IPRs, three main interlinking concepts have been developed by the ECJ in its case law.²¹⁷

(i) First, the Court has drawn a distinction between the *existence* of IPRs and their *exercise* – whereas the existence of rights is unaffected by the Treaty, their exercise may be.

(ii) Second, the Court has developed the idea that there is a *specific subject-matter* of each kind of right, the protection of which is justified even if it leads to restrictions on inter-Member State trade. In other words, the exercise of IPRs, which partitions the market, will be allowed in so far as it is necessary to protect the specific subject-matter.

(iii) Lastly, it has built up a jurisprudence on the *exhaustion of rights*. Once a rights holder has consented to the marketing of the protected product within the Community, the rights encompassed in the specific subject-matter are exhausted with the effect that the holder cannot rely on national rights to prevent the movement of the goods between Member States.

5.1.1 The Existence v. Exercise Dichotomy

The ECJ has in several cases made it clear that owners of IPRs do not enjoy a complete immunity in the exclusive exploitation of their rights under the EC Treaty.²¹⁸ The distinction between *existence* and *exercise* was introduced already in 1966 in *Consten & Grundig*.²¹⁹ The case concerned an exclusive distribution agreement, which appointed Consten to be Grundig's exclusive distributor in France and allowed Consten to register its trademark GINT there. The provisions of the agreement and the registration of the trademark had the effect of conferring absolute territorial protection on Consten by enabling it to prevent parallel imports of Grundig's products into France through proceedings for trademark infringement. The Court held

²¹⁷ See Jones & Sufrin, pp. 561-67.

²¹⁸ The main area of tension between IPRs and Article 82 has been the question whether it is an abuse for a dominant undertaking to refuse to allow others to use its rights. See in particular Case 238/87, *Volvo AB v. Erik Veng* [1988] ECR 6211, Case 53/87, *CICRA v. Renault* [1988] ECR 6039, Cases C-241-241/91 *P RTE & ITP v. Commission* [1995] ECR I-743 (*Magill*), Case Case T-504/93, *Tiercé Ladbroke SA v. Commission* [1997] ECR II-293, Case Case-7/97 *Oscar Bronner GmbH & Co. KG v. Mediaprint* [1998] ECR I-7791. See Jones & Sufrin pp. 622-628. See also the more recent Case COMP/C 3/37.792 *Microsoft-Antitrust* [2004] EC Comm.1.

²¹⁹ Cases 56 & 58/64, *Consten & Grundig v. Commission* [1966] ECR 229.

that the Commission's condemnation of the arrangements did not affect the grant of the trademark rights but 'only limits their exercise'.²²⁰

Since then, the case law on the exercise of exclusive rights including IPRs by dominant undertakings has developed into one of the most controversial areas in EC competition law.²²¹ Until recently, however, the precedents mainly focused on the question as to whether the grant of compulsory licences for IPRs could be imposed on dominant undertakings by competition authorities. In this respect, the ECJ ruled in various landmark cases, most notably *Magill* and *Bronner*, that the exercise of an exclusive right and, more specifically, that the refusal by a company holding a dominant position to grant a licence for an IPR may, in certain exceptional circumstances, constitute an abuse of a dominant position.²²² Hence, under 'exceptional circumstances' and where a particular exercise of IPRs by their owners conflicts with Article 82 of the Treaty, EC competition authorities reserve the right to order a compulsory licence.²²³

In 2004, the ECJ delivered its judgment in *IMS*.²²⁴ This case is of central importance as it illustrates the ECJ's current approach in relation to the 'essential facilities doctrine' in a context where the facility in question is protected by IPRs. In its judgment, the ECJ repeated the assessment contained in *Bronner*,²²⁵ according to which the application of the doctrine requires a demonstration that the replication of a similar facility by a company of comparable size would not be economically viable. The ECJ added that a factor that should be taken into account by the national court when assessing whether the copyright was essential was whether the participation by customers in the development of the facility constituted an additional barrier to the creation of a competing facility. On the refusal to licence issue, the ECJ held that for a refusal to be regarded as abusive it must not only (i) prevent the emergence of a *new product* or service for which there is a potential demand and (ii) be without objective justification, but also (iii) be capable of eliminating all competition on the relevant market.²²⁶

²²⁰ This distinction drawn between the grant of rights and their exercise was elaborated further in Case 78/70 *Deutsche Grammophon Gesellschaft v. Metro-SB-Großmärkte GmbH* [1971] ECR 487.

²²¹ It is often argued that the distinction between the existence and exercise of rights is not convincing. A property right which cannot be exercised has no value. IPRs are valuable because they enable the holder to exercise rights which prevent third parties from committing infringing acts. If Community law limits the holder's ability to control third parties then the value of the right is diminished, and the fact that the 'existence' of the right is untouched is of little comfort. Arguably the existence/exercise dichotomy is simply a flexible tool developed by the ECJ which enables it to make policy decisions under the guise of principle.

²²² See Joined Cases C 241/91 P & 242/91 P, *Magill* [1995] E.C.R. I-743; Case C-7/97, *Bronner* [1998] E.C.R. I-7791.

²²³ See Eccles & Ferla, p. 7.

²²⁴ See Case C-418/01, *IMS Health v NDC Health GmbH & Co KG*, 29 April 2004. See also Eccles & Ferla, pp. 6-7.

²²⁵ Case C-7/97 *Oscar Bronner GmbH & Co. KG v. Mediaprint* [1998] ECR I-7791.

²²⁶ Unfortunately, the concept of a 'new product' was not elaborated on and remains for the national court to define. See Eccles & Ferla, p. 7. See also Henemann, 'Compulsory Licences and Product Integration in European Competition Law - Assessment of the European Commission's Microsoft Decision', IIC 2005 Heft 1, 63 f., pp. 70-71.

As regards the Commission's current review of Article 82, as a result of which it is thought to adopt a more economics based approach to allegedly abusive practices, it is worth noting that the 2005 Report by the Economic Advisory Group for Competition Policy (EAGCP) in the context of refusal-to-deal cases pointed out that 'the competition authority should be particularly reluctant to interfere when the source of the bottleneck is an intellectual property right' since such intervention may reduce 'the incentives to innovate'. Indeed, the EAGCP indicated that '[IPRs] have been granted by the state in order to create market power and to give innovators a reward to their efforts' and that 'it is inconsistent if the state interferes with these rights ex post and takes market power away'.²²⁷

5.1.2 The Specific Subject-Matter

In order to draw the appropriate line of demarcation between IP protection and the Community goal of free movement of goods, the ECJ has sought to identify the core value – or essential function – of the various IPRs. Arguably, this delineation is just as relevant in the context of IP protection and competition.

In *Centrafarm v. Sterling Drug*²²⁸ the Court first defined the *specific subject-matter of a patent* as 'the guarantee that the patentee, to reward the creative effort of the inventor, has the *exclusive right to use an invention* with a view to manufacturing industrial products and *putting them into circulation for the first time*, either directly or by the grant of licences to third parties, as well as *the right to oppose infringements*.'²²⁹

5.1.3 Exhaustion of Rights

Apart from the exclusive right to use the invention and to defend the patent right against infringements, the specific subject-matter of a patent thus entails the right to put the patented product on the market for the first time. Despite its hindrance to inter-member state trade, the exclusive right to do this is seen as necessary to reward the inventor for its creative effort. However, under the so-called 'exhaustion of rights doctrine', once the patentee has consented to placing the product on the Community market,²³⁰ s/he has *exhausted* the rights encompassed in the specific subject-matter and

Note in this context, the comment that a generic copy, by its very nature, duplicates an existing product (albeit that it may be available at a lower price) and thus cannot constitute a new product. See Sophie Lawrance and Pat Treacy, 'The Commission's AstraZeneca Decision: Delaying Generic Entry is an Abuse of A Dominant Position', J.I.P.L.P., 2005, Vol. 1, No. 1, p. 7, at p. 9. Compare the *AstraZeneca* decision.

²²⁷ The EAGCP report is available at

http://europa.eu.int/comm/competition/publications/studies/eagcp_july_21_05.pdf.

²²⁸ Case 15/74 *Centrafarm v. Sterling Drugs* [1974] ECR 1147.

²²⁹ Id. para. 9 (emphasis added).

²³⁰ The 'Community' should be interpreted in this context to mean the whole EEA. The EEA is the relevant area by virtue of Prot. 28 of the EEA Agreement, which provides for exhaustion throughout the EEA in accordance with the case law of the Court.

cannot prevent the product moving freely within the Community.²³¹ Obviously, the effect of the doctrine has been to severely limit the ways in which holders of parallel patents in different Member States may exploit their rights. In particular, it has had that effect on the trade in pharmaceuticals, where price differentials between Member States are common.²³²

Common for the three concepts developed above is that they all have had far-reaching implications on the IP-antitrust relationship in the Community. In particular, the scope within which a patentee may legitimately enjoy and defend his exclusive IPR has been significantly narrowed.

In the *AstraZeneca* decision examined below, the Commission has arguably gone beyond these existing precedents by enlarging the range of abusive conduct in relation to exclusive rights. As will be seen, the Decision does not only concern the abusive exercise of IPRs, but also the abusive obtaining, extension and, above all, protection of the rights themselves.²³³

5.2 The US Approach

The last three decades have seen great changes in the attitudes of the FTC and DoJ in relation to the role of IP in the competitive process. These have pended from systematic suspicion of IP licensing in the 1970s to a very lenient approach in the 1980s, to the more recent view that transactions involving IP will most often promote, rather than restrain, competition.²³⁴

An illustrative example of this more recent pro-IP view is the *IP Guidelines* issued in 1995,²³⁵ in which the agencies clarified their enforcement position in relation to restraints in IP licensing arrangements. These stipulate that, in most cases, licensing restraints are to be evaluated under the *rule of reason* i.e., by comparing a restraint's pro- and anti-competitive effects. However, certain categories of restraints are 'so plainly anticompetitive that [they] should be treated as unlawful *per se* without an elaborate inquiry into [their] likely competitive effects'.²³⁶ The IP Guidelines also establish *safe harbours* in which conduct is considered lawful, in the absence of

²³¹ That the exhaustion of rights doctrine is based on the idea of consent means that the patentee, if s/he has consented to the first marketing of the protected product in the Community, cannot prevent its circulation within the Community by relying on national IPRs. The patent holder is thought to have exhausted her/his rights as soon as s/he has had the opportunity to reap the rewards of the first marketing of the product. However, there is neither consent for the purposes of the exhaustion of rights doctrine where the patentee is legally bound to market the products in the exporting State (See cases C-267-268/95, *Merck v. Primetown* [1996] ECR I-6285, at paras. 49-50), nor where the patentee has been forced to give compulsory licence by national law (Case 19/84), *Pharmon v. Hoechst* [1985] ECR 2281. See Jones & Sufrin, pp. 561-67.

²³² In *Centrafarm*, the Court expressly denied the right of the patentee to command higher prices in one Member State than in another. See, paras. 22-25.

²³³ Compare Gunther & Breuvert, p. 679.

²³⁴ See Eccles & Ferla, p. 1.

²³⁵ See the US DoJ and FTC 'Antitrust Guidelines for the Licensing of IP' (1995), above.

²³⁶ Section 3.4, IP Guidelines (emphasis added).

extraordinary circumstances.²³⁷ Moreover, they provide the agencies' general views on specific types of licensing arrangements.²³⁸

5.2.1 The Patent Right & Its Core

In the US, the 'core' of the patent is thought to be the patentee's right to exclude others from making, using, or selling a protected invention. As long as the patent holder remains within the legitimate confines of the patent, there is a shield that precludes liability under the US antitrust laws. To some extent, a patent can therefore be viewed as a statutorily authorised exception to the general rule prohibiting monopolization, conferring on its owner a form of immunity from antitrust liability.

As far as *refusals to license* are concerned, the traditional US view that the unconditional and unilateral refusal by an IP owner to license its IPRs is justified, was reinforced by declarations made by representatives of the agencies in 2004. In a comment on the Supreme Court decision in *Trinko*,²³⁹ it was stated that the case 'clarified that there is no basis in US antitrust law for a stand-alone essential facilities doctrine'. Moreover, 'profound scepticism [was expressed] that the antitrust laws were intended to create a duty by one competitor to assist its competitors by assuring them access to its tangible or intellectual property'.²⁴⁰ In another comment citing *Trinko*, it was stated that while 'compulsory licensing as a merger remedy is a well-established tool [...] non-merger compulsory licensing imposed by an agency or the courts should be a rare beast' due to the difficulty of administering the remedy and the possibility of reducing innovation incentives.²⁴¹ Clearly, this reflects a US approach that is highly critical to compulsory licences of IPRs. Consequently, US competition agencies and courts (unlike the EC competition authorities who occasionally have analysed refusals to licence IPRs as abuse of dominance) practically never treat refusals to deal as antitrust violations.²⁴²

However, this does not mean that a US patentee's immunity from antitrust liability is absolute. Where the patent holder goes 'beyond the limited monopoly which is granted, the arrangements by which the patent is utilized are subject to general law [...]. The possession of a valid patent or patents

²³⁷ The safe harbours differ according to whether the relevant market is a goods market, a technology market or an innovation market. As far as innovation markets are concerned, a proposed licensing arrangement falls within the safe harbour if it is not facially anti-competitive and there are at least four independently controlled entities, in addition to the parties, that have the incentive, assets and characteristics necessary to engage in R&D that is a close substitute for the activities of licensee and licensor.

²³⁸ See Section 5.2-6, 1995 IP Guidelines.

²³⁹ *Verizon Communications Inc v Law Offices of Curtis v Trinko LLP* (2004 WL 51011 (2004)).

²⁴⁰ See Assistant Attorney General R Hewitt Pate commenting on *Trinko* at www.usdoj.gov/atr/public/speeches/205389.htm. Visited on June 20, 2007.

²⁴¹ See Deputy Assistant Attorney General for Antitrust Policy Makan Delrahim at www.usdoj.gov/atr/public/speeches/203627.htm. Visited on June 20, 2007.

²⁴² Eccles & Ferla, p. 4.

does not give the patentee any exemption from the provisions of the Sherman Act beyond the limits of the patent monopoly.²⁴³

As will be seen below, if a patentee e.g. initiates litigation seeking to enforce a patent that is known by her/him to be invalid, such action can be an unlawful attempt to monopolize under section 2 of the Sherman Act.²⁴⁴

Since there would be no valid patent to serve as a shield against the antitrust laws, there would be nothing preventing the conduct from being measured under basic antitrust principles. As a result, the defendant could not only enter a counterclaim seeking relief under the antitrust laws, but could also assert the defence of 'patent misuse'.²⁴⁵

5.2.2 The Patent Misuse Doctrine

In the US, the courts have found certain actions by patentees that do not necessarily violate the antitrust laws to be improper and constitute IP *misuse*.²⁴⁶ The misuse concept originated in the patent area as a defence to patent infringement,²⁴⁷ and was intended to prevent the patentee from extending the power of the patent beyond the grant defined in the patent claims.²⁴⁸ The doctrine is equitable in nature and arises out of the defence of 'unclean hands'. Rather than rendering a patent invalid, the misuse defence renders the patent unenforceable until the abusive practice has been abandoned and the effects of the practice have dissipated.²⁴⁹

The first application of the principle of patent misuse was in the case of *Motion Picture Patents*.²⁵⁰ The Court further developed the doctrine in a series of cases, *Carbice*, *Leitch*, *Morton Salt* and *Mercoid* against a backdrop of continued national concern about the use of patents.²⁵¹

²⁴³ *Unitherm Food Sys., Inc. v Swift-Eckrich, Inc.* 375 F.3d 1357 (quoting *United States v Springer Mfg Co.*, 374 U.S. 174, 196-97 (1963)).

²⁴⁴ NB: If the action is brought by the FTC the anticompetitive behaviour may be contrary to Section 5 of the Federal Trade Commission Act. See Gunther & Breuvert, p. 672.

²⁴⁵ Arnold B. Silverman, 'Patent Misuse: Limitations on a Patentee's Rights', JOM, 44 (8) (1992), pp. 54-55. Available at <http://www.tms.org/pubs/journals/JOM/matters/matters-9208.html>, visited on April 26 2007.

²⁴⁶ Balto & Wolman, p. 79.

²⁴⁷ That is, rather than being a basis for an affirmative damages suit, misuse constitutes a defence in a suit for infringement. See *Windsurfing Int'l, Inc. v. AMF, Inc.*, 782 F.2d 995, 1001 (Fed.Cir.1986); *Virginia Panel Corp. v. MAC Panel Co.*, 133 F.3d 860, 868- 69 (Fed. Cir. 1997) in Balto & Wolman, p. 80.

²⁴⁸ See *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1372 (Fed. Cir. 1998): 'The key inquiry is whether, by imposing conditions that derive their force from the patent, the patentee has impermissibly broadened the scope of the patent grant with anticompetitive effect.' See Balto & Wolman, p. 79.

²⁴⁹ See Balto & Wolman, p. 80. See also Robin Feldman, 'Should We Breathe Life into Patent Misuse?', Hastings College of Law, pp. 4-5.

²⁵⁰ *Motion Picture Patents Co. v. Universal Film Mfg.*, 235 F. 398 (2d. Cir. 1916). See 'Contributory Infringement and Misuse – The Effect of Section 271 of the Patent Act of 1952', 66 Harv. L Rev. 909, 911 (1953).

²⁵¹ See *Carbice Corp. v. American Patents Dev. Corp.*, 283 U.S. 27 (1931); *Leitch Mfg. v. Barber Co.*, 302 U.S. 458 (1938); *Morton Salt Co. v. G.S. Suppiger Co.*, 314 U.S. 488 (1942); *Mercoid Corp. v. Mid-Continent Inv. Co.*, 320 U.S. 661, 668 n. 1 (1944).

By the mid-1940s, the Supreme Court had delineated the basic outline of patent misuse – *a patent holder commits patent misuse by trying to improperly extend the time or scope of the patent grant.*²⁵²

Although it was not originally a prerequisite to prove misuse, Federal Circuit case law and legislation now require a showing of injury for most types of misuse.²⁵³

Generally, misuse is held to exist where the patentee has either engaged in conduct involving the patent that amounts to a violation of the antitrust laws or has improperly sought to expand the scope of the patent (either in a physical or temporal sense).²⁵⁴

Since the Supreme Court's ruling in *Morton Salt*, it has been clear that patent misuse does not require a violation of the antitrust laws. Thus, while violations of the antitrust laws involving patents also involve patent misuse, there can be misuse without violating antitrust laws.²⁵⁵ This notion is consistent with the view that patent misuse is tested under patent policy, not antitrust policy.²⁵⁶

Some commentators believe that the misuse doctrine is unnecessary. Because the antitrust laws are intended to separate procompetitive from anticompetitive conduct, it is not clear what rational economic policy is furthered by using the misuse doctrine to punish conduct when there is no violation of the antitrust laws.²⁵⁷

²⁵² See 'Patents – Extent of Use of Patent Use of Tying Agreement Bars Patentee in *Infringement Suit*', 9U. Chi. L. Rev. 518, 520 (1941-42). See Robin Feldman, pp. 13-15.

²⁵³ Balto & Wolman, p. 80.

²⁵⁴ Arnold B. Silverman, p. 54.

²⁵⁵ See *Morton Salt*, 490, 492.

²⁵⁶ See Robin Feldman, pp. 13-15; Arnold B. Silverman, p. 55.

²⁵⁷ See Roger B. Andewelt, 'Competition Policy and the Patent Misuse Doctrine', 25 Pat. Trademark & Copy. J. 41, 42 (1982). See Balto & Wolman, p. 80.

6 Procedural Issues

As was seen above, IP law stimulates the creation and distribution of information and products that are vital to economic growth and wellbeing.²⁵⁸ The negative side to it is that it also may promote harmful litigation by IP owners who seek to profit from *opportunistic* and *anti-competitive lawsuits*.²⁵⁹ In fact, some seem to value their IPRs primarily as tickets into court, enabling them to sue IP users. This, taken together with the fact that the rights are relatively easy to acquire and have a potentially broad application, has made harmful IP litigation a common phenomenon. Moreover, the problem is intensifying due to the expansion of the scope and strength of IP law on both sides of the Atlantic.²⁶⁰

More specifically, *harmful IP litigation* may arise when a party (i) seeks to enforce an IPR that is probably invalid or (ii) seeks to stretch a valid right to cover activities outside the proper scope of the right. In other words, the activity it is based on making a 'weak lawsuit' look credible.²⁶¹

A *weak lawsuit* is generally viewed as one in which the objective probability of success (i.e. of proving infringement) is low at the time of filing. This is evaluated using the knowledge of a hypothetical plaintiff who files after conducting a reasonable investigation.²⁶² Moreover, a weak lawsuit may be classified as *anticompetitive* if the defendant's alleged infringing behaviour occurs in a market the plaintiff participates in or intends to enter – otherwise, it may be classified as *opportunistic*.

Whereas a plaintiff usually files an *anticompetitive lawsuit* seeking to impair the defendant's performance in their shared market, or even to exclude the defendant from the market completely, a plaintiff generally files an *opportunistic* lawsuit seeking a settlement payment.²⁶³

Although it may seem hard to understand why rational defendants succumb to the threat of weak IP suits, three reasons may be presented to show why such lawsuits may seem credible:²⁶⁴

²⁵⁸ See Robert E. Evenson & Sunil Kanwar, 'Does Intellectual Property Protection Spur Technological Change?' 3 Econ. Growth Ctr., Yale Univ., Center Discussion Paper No. 831, June 2001, available at http://papers.ssrn.com/so13/papers.cfm?abstract_id=275322#Paper%20Download.

²⁵⁹ See Meurer, p. 509.

²⁶⁰ Robert P. Merges, 'One Hundred Years of Solicitude: Intellectual Property Law, 1900-2000', 88 Cal. L. Rev. 2187, 2239-40 (2000) (asserting that the belief that economic policy should be grounded in a competitive baseline is starting to give way to a notion that all sorts of intangibles deserve protection from some form of property law).

²⁶¹ See Meurer, p. 509.

²⁶² See Meurer, p. 512. Compare Robert G. Bone, 'Modelling Frivolous Suits', 145 U. Pa. L. Rev. 519, 533 (1997) (stating that a lawsuit is frivolous '(1) when a plaintiff files knowing facts that establish complete (or virtually complete) absence of merit as an objective matter on the legal theories alleged, or (2) when a plaintiff files without conducting a reasonable investigation which, if conducted, would place the lawsuit in prong (1).').

²⁶³ See e.g. Chris Guthrie, 'Framing Frivolous Litigation: A Psychological Theory', 67 U. Chi. L. Rev. 163 (2000).

²⁶⁴ See Meurer, pp. 512-13.

(i) First, the scope of IPRs is far from fixed. Disagreement as to the proper interpretation of patent claims, vague standards of infringement, conflicting expert testimony and the complexity of the evidence are all factors that make trial errors in IP litigation not only possible, but also difficult to detect.²⁶⁵ Also, high variance in the scope of IPRs makes it lucrative for plaintiffs with narrow IPRs to take the chance that a court will grant them broad rights.²⁶⁶

(ii) Second, a weak lawsuit may present a credible threat to a defendant who has trouble distinguishing weak lawsuits from strong ones.²⁶⁷ Particularly in the early stages of IP litigation the plaintiff is likely to have better information about the scope and validity of the IPRs than the defendant and may thus ‘bluff’ the defendant into leaving the market. *Walker Process*²⁶⁸ illustrates the role of asymmetric information in making weak lawsuits credible. In this case, Food Machinery was granted a process patent by fraudulently concealing information about prior use. When Walker entered the market, Food Machinery filed a patent infringement lawsuit. However, due to the fact that Walker uncovered evidence of the prior use and proved the patent was invalid, Food Machinery failed in its attempt to bluff its new rival out of the market.²⁶⁹ Although successful bluffs are bound to pass unnoticed, it seems very likely that many similar attempts succeed in deterring market entry or forcing a restrictive license onto an entrant.²⁷⁰

(iii) Finally, a weak lawsuit may be credible because of the costs it may impose on the defendant.²⁷¹ Whereas a defendant may settle an *opportunistic* lawsuit to avoid the nuisance of mounting a defence, a defendant may settle an *anticompetitive* suit because the cost of a defence threatens the defendant's solvency.²⁷² Particularly, if a plaintiff establishes a

²⁶⁵ A weak lawsuit is credible if the court is likely to err in favour of the plaintiff. Even though the defendant recognizes that she should win at trial, if the risk of error is high enough, then the plaintiff holds a credible threat. See Meurer p. 513.

²⁶⁶ Robert C. Nissen, ‘*The Art of the Counterclaim: Festo Won't End Frivolous Infringement Cases, But It Does Make It Easier to Fight Back*’, *Intell. Prop.*, May 7, 2001, at 64 (‘Defending against frivolous infringement allegations can be a nightmare. At best, after spending hundreds of thousands or even millions of dollars, a defendant is restored to the position it held before the case was filed. At worst, a defendant is found liable because the jury was bewildered by the complex technologies at issue.’)

²⁶⁷ For a model of patent litigation in which plaintiffs with weak claims can successfully bluff their way to a settlement payment, see generally Michael J. Meurer, ‘*The Settlement of Patent Litigation*’, 20 *Rand J. Econ.* 77 (1989). See Meurer, p. 514.

²⁶⁸ See *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.* 382 U.S. 172, 178 (1965).

²⁶⁹ *Id.* at 174.

²⁷⁰ See Robert H. Bork, ‘*The Antitrust Paradox: A Policy at War with Itself*’ 347 (1978) (expressing concern about the threat of predation through Walker Process-type fraud); Gary Myers, ‘*Litigation as a Predatory Practice*’, 80 *KY. L.J.* 565, 594 (1992) (noting that litigation can be used to prevent or delay a competitor's entry into a market).

²⁷¹ See Meurer, p. 515.

²⁷² Note that IP cases often do impose much higher litigation costs on defendants than plaintiffs. One source of asymmetry arises from disruption of the defendant's business caused by preliminary injunctions and other factors. Another asymmetry arises because some plaintiffs sue multiple defendants and spread the cost of litigation across those cases. See, e.g., Lucian Arye Bebchuk, ‘*A New Theory Concerning the Credibility and Success of Threats to Sue*’, 25 *J. Legal Stud.* 371, 373 (1996).

predatory reputation for prosecuting weak suits through to the end, the threat of a weak lawsuit may effectively deter entry into the market.²⁷³

Upon a comparison with other predatory behaviour, it seems that predatory litigation is more likely to succeed.²⁷⁴ Predatory litigation (although it has not been studied as closely as predatory pricing) has the advantage over predatory pricing that the cost to the predator declines after the first lawsuit – the plaintiff can use the work product from the first litigation in subsequent litigation.²⁷⁵

As far as *opportunistic* IP litigation is concerned, there are strong indications suggesting that the problem is serious and even getting worse:²⁷⁶

(i) First, as a consequence of IP becoming more valuable and as the number of IPRs – especially patents – are increasing rapidly, the rate of IP litigation has grown proportionately.²⁷⁷ Under these conditions, opportunistic suits tend to increase simply because the large number of legitimate cases makes the opportunistic ones easier to conceal.

(ii) Second, a growing market for the sale of IPRs promotes opportunistic IP litigation by making it easier for those who try to bluff their way to large settlement payments to enter the market.²⁷⁸

(iii) Finally, in recent years patent plaintiffs (particularly in the US) have been effectively organized and financed by specialists in patent litigation

²⁷³ Generally, a plaintiff is more likely to succeed by bringing a sequence of frivolous suits than by bringing an isolated suit. Partly, this is because the plaintiff then can develop a reputation for imposing costs on defendants (even if that also means costs to the plaintiff). The reputation for being ‘tough’ makes the frivolous claim more credible and more valuable. See Reinhard Selten, ‘*The Chain Store Paradox*’, 9 *Theory & Decision* 127 (1978). See also Patrick Bolton et al., ‘*Predatory Pricing: Strategic Theory and Legal Policy*’, 88 *Geo. L.J.* 2239, 2300-01 (2000) (describing reputation effect predation). For a non-IP example of bad faith litigation deterring entry, see *Otter Tail Power Co. v. United States*, 410 U.S. 366, 368 (1973) (noting that power company maintained monopoly by using litigation to prevent rival's entry). See Meurer, pp. 515 and 518.

²⁷⁴ Predatory litigation is more difficult to detect, especially when the lawsuit has some merit. See generally Michael W. Bien, ‘*Litigation as an Antitrust Violation: Conflict Between the First Amendment and the Sherman Act*’, 16 *U.S.F. L. Rev.* 41 (1981).

²⁷⁵ Predatory pricing might place greater costs on the predator than the prey because the predator suffers a loss across a larger share of the market. By way of contrast, predatory litigation favours the plaintiff because the plaintiff gets to choose the forum and the initial direction of the discovery. See Gary Myers, at 597-99.

²⁷⁶ See Meurer, pp. 513-16.

²⁷⁷ Brenda Sandburg, ‘*A New Industry Transforms the Patent System: Congress, Corporations Eye Reform as Power of Patent Enforcers Grows*’, *The Recorder*, July 30, 2001, at <http://www.law.com> (‘With the growth in patent licensing, the number of patent suits has doubled in the past decade, from 1,171 in 1991 to 2,484 in 2000, according to data compiled by Paul Janicke, a professor at the University of Houston Law Center.’). Visited on June 20, 2007. Del Jones, ‘*Businesses Battle Over Intellectual Property: Courts Choked with Lawsuits to Protect Ideas and Profits*’, *USA Today*, Aug. 2, 2000, at 1B, available at 2000 WL 5785645 (describing the flood of patent litigation).

Similar trends may be observed in parts of the EC, see ‘*Patent Litigation Insurance – A Study for the European Commission on the Feasibility of Possible Insurance Schemes against Patent Litigation Risks*’, *Final Report* June 2006, p. 13.

²⁷⁸ Brenda Sandburg, ‘*Patent Blockbuster Goes to High Court: IP attorneys looking to U.S. Supreme Court to clear up confusion over Festo*’ *The Recorder*, June 18, 2001, at <http://www.law.com> (‘[T]here are companies that buy a patent for \$50,000 at a bankruptcy auction and then decide to sue the world for it...’). Visited on June 20, 2007.

and licensing. Patent lawsuit investors buy interests in the patents, join as plaintiffs and receive compensation for whatever reward the lawsuit brings.²⁷⁹ Alternatively, patent litigation is done on a contingency basis with percentages as high as 45 per cent.²⁸⁰

There is no doubt that opportunistic IP suits impose direct and indirect costs on defendants and society.²⁸¹ Apart from settlement payments, there are direct legal costs and indirect costs borne by potential defendants who work to minimize their exposure to opportunistic litigation.²⁸² That way, opportunistic patent cases may deter firms from entering new markets or adopting new product features or designs.²⁸³

As regards *anticompetitive* IP litigation, this has long been a frequently used tool for strong firms to exclude their weaker rivals from the market. Although exclusionary litigation to a certain extent can be a socially desirable way to secure a reward to innovative firms, there is a fine line between this and socially undesirable exclusion.²⁸⁴ Anticompetitive suits will achieve harmful exclusionary outcomes where defendants settle because they fear the plaintiff's IPR will be construed too broadly, or because they lack information proving the plaintiff's right is invalid.

Undesirable exclusionary outcomes will also be achieved where defendants may be confident that the plaintiff will lose the lawsuit, but still settle simply to avoid the costs of litigation.²⁸⁵ Apart from gaining a favourable settlement, the owner of a weak IPR may in such cases thus succeed in deterring competitors from using his IP because of the threat of suit.²⁸⁶ While successful anti-competitive IP litigation does not leave any traces,

²⁷⁹ See Linda Himelstein, 'Investors Wanted For Lawsuits', *Bus. WK.*, Nov. 15, 1993, at 78; Susan Lorde Martin, 'Financing Plaintiffs' Lawsuits: An Increasingly Popular (and Legal) Business', 33 *U. Mich. J.L. Reform* 57, 58 (2000).

²⁸⁰ Meurer, p. 520, fn. 69.

²⁸¹ Defendants who fear the high cost of IP litigation often settle opportunistic claims to avoid that cost. To the extent that settlement payment to end frivolous lawsuits distort the decision of a firm to enter a market protected by IPRs because of the fear of litigation they also cause a social loss.

²⁸² Amy Harmon, 'Suddenly, 'Idea Wars' Take on a New Global Urgency', *N.Y. Times*, Nov. 11, 2001, at 4A 30, available at <http://www.nytimes.com/2001/11/11/business/11PROP.html> (reporting that patent litigation cost American companies \$4 billion in the year 2000), visited on June 20, 2007; Large firms that fear frequent opportunistic suits may (thanks to financial resources etc.) be able to develop an effective reputation as 'tough defendants'. Conversely, small firms might be much more vulnerable to opportunistic suits and most often represent weak defendants.

²⁸³ Meurer, p. 519.

²⁸⁴ In *Grip-Pak, Inc. v. Illinois Tool Works, Inc.*, Judge Posner wrote that 'litigation could be used for improper purposes even when there is probable cause for the litigation; and if the improper purpose is to use litigation as a tool for suppressing competition in its antitrust sense, it becomes a matter of antitrust concern.' 694 F.2d 466, 472 (7th Cir. 1982).

²⁸⁵ Meurer, p. 521.

²⁸⁶ See *Grip-Pak*: '[M]any claims not wholly groundless would never be sued on for their own sake; the stakes, discounted by the probability of winning, would be too low to repay the investment in litigation.'

there are many cases where exclusion failed.²⁸⁷ One example is *Handguards, Inc. v. Ethicon*.²⁸⁸ In this US case, the patent plaintiff Ethicon controlled 90 per cent of the market for plastic gloves. Ethicon knew the patent was invalid because of an earlier inventor and prior use, but tried to preserve its dominant position by suing an entrant, Handguards, for patent infringement.²⁸⁹ However, to Ethicon's dismay, Handguards discovered evidence of the inequitable behaviour and thus invalidated the patent.

Even where not entirely successful, predatory litigation has a negative impact on a company's cash flow because of the high cost of IP litigation and a variety of other indirect costs. This may be a serious problem especially for smaller defendants who are new in the business.²⁹⁰

For the predator, costly predatory tactics are irrational unless the predator can recoup its litigation cost.²⁹¹ Such recoupment is much facilitated by a preliminary injunction and the like. Ultimately, however, the predator hopes to more than recoup its cost of litigation by reducing competition and raising prices. Obviously, this is most likely to occur when the plaintiff has greater financial resources than the defendant.²⁹²

Arguably, harmful litigation of the types described above can and should be controlled. Apart from measures that reduce the risk that parties will acquire invalid IPRs and which make the scope of IPRs clearer, a mix of procedural and substantive measures may have to be taken to mitigate the harm caused.²⁹³ However, to the extent that such measures aim at targeting the illegitimate use of the court process, utmost care will have to be taken so as not to interfere with the basic human right of access to the courts, which ensures the rule of law and represents one of the cornerstones of the democratic state.

²⁸⁷ See *Bayer AG v. Biovail Corp.*, No. 200-CV-128-WCO, 2001 U.S. Dist. LEXIS 23907, at *12 (N.D. Ga. Mar. 27, 2001) (addressing allegedly baseless patent infringement by Bayer to block competition from generic drug).

²⁸⁸ *Handguards, Inc. v. Ethicon* 743 F.2d 1282 (9th Cir. 1984).

²⁸⁹ *Id.* at 1294 and at 1288.

²⁹⁰ Litigation can sour a defendant's credit rating. A predatory plaintiff can divert customers from a defendant by threatening the defendant's customers with a lawsuit. Furthermore, the plaintiff can use a preliminary injunction to block the defendant's production and sales before trial. See *Handguards, Inc. v. Ethicon, Inc.*, 601 F.2d 986, 991 (9th Cir. 1979) (claiming that Ethicon, the defendant, 'had generated adverse publicity regarding its infringement actions, [...] threatening potential customers of the plaintiff, with the result that vital corporate resources were committed to defence of the infringement actions, Handguards' relations with potential customers were impaired, a proposed joint venture was aborted, and the company found itself unable to obtain outside financing necessary for it to remain competitive in the industry. '); See also Jean O. Lanjouw & Josh Lerner, 'Tilting the Table? The Use of Preliminary Injunctions', 44 J.L. & Econ. 573, 591 (2001) (stating that smaller firms have higher litigation costs and suffer greater indirect costs caused by the dilution of management's equity ownership).

²⁹¹ See generally *Brooke Group Ltd. v. Brown Williamson Tobacco Corp.*, 509 U.S. 209 (1993).

²⁹² Meurer, pp. 524-25.

²⁹³ See Meurer, p. 509.

6.1 The Right of Access to the Courts

In the EC, the responsibility for ensuring the individual's right of access to the courts lies on a national level. However, the ability to assert one's rights through the courts has been recognised by the ECJ to express a general principle of law, which underlies the constitutional traditions common to the Member States.²⁹⁴ The right is also laid down in Articles 6 and 13 of the European Convention for the Protection of Human Rights and Fundamental Freedoms (ECHR). Through the Maastricht Treaty, the ECHR was incorporated into Community law through Article 6.2.

In the US, the right of access to the courts is one aspect of the right of petition.²⁹⁵ This right is guaranteed by the First Amendment to the Constitution of 1787, which specifically prohibits Congress from, amongst others, abridging 'the right of the people [...] to petition the Government for redress of grievances.'²⁹⁶ The ability to petition the government (including the right of access to courts) is thus one of the pre-eminent rights granted under the Bill of Rights.²⁹⁷

6.2 Abuse of Process

Although access to the courts is a fundamental right and a general principle ensuring the rule of law, most legal systems agree that, in exceptional circumstances, it may be legitimate to curtail that right. Where, for example, the judicial process is used for an illegitimate purpose and unfounded legal proceedings are brought as a means of harassing, threatening, weakening or eliminating the opponent, the general rule of access to the courts may be restricted under various *abuse of process doctrines*. Common for these doctrines is that they protect the integrity of the judicial process by limiting abuses of the judicial system. In other words, they are designed to prevent use of the judicial process as an anticompetitive weapon.

²⁹⁴ Case T-111/96 *ITT Promedia NV / Commission* [1998] ECR II s. 2941, pp. 1 and 11.

The right of access to courts was also emphasised in Case 222/84, *Johnston / Chief Constable of the Royal Ulster Constabulary*, [1986] ECR s. 1651, pp. 17-18..

²⁹⁵ See *California Motor Transport Co. v. Trucking Unlimited*, 404 U.S. 508 (1972), at 510. The right to petition the government has been interpreted as extending to petitions of all three branches: the Congress, the executive and the judiciary. See S.W. O'Donnell, 'Unified Theory of Antitrust Counterclaims in Patent Litigation', *Virginia Journal of Law & Technology* Summer 2004, p. 1.

²⁹⁶ The *First Amendment* to the US Constitution is a part of the US *Bill of Rights* (Article the third, [amendment one], available at <http://www.constitution.org/cons/constitu.htm> (visited on June 20, 2007). It prohibits the federal legislature from making laws that establish religion or prohibit free exercise of religion, laws that infringe the freedom of speech, infringe the freedom of the press, limit the right to assemble peaceably, or limit the right to petition the government for a redress of grievances. Although the First Amendment only explicitly prohibits the named rights from being abridged by laws made by Congress, the courts have interpreted it as applying more broadly. In the last decades, the right to petition has e.g. been construed to include the right to bring suits in the US courts.

²⁹⁷ The *Bill of Rights* comprises the first ten amendments to the Constitution, adopted between 1789 and 1791, all of which relate to limiting the power of the federal government.

6.2.1 Abuse of Process in the US Legal System

Three US *Abuse of process doctrines* limit abuses of the judicial system by imposing sanctions when a plaintiff litigates in bad faith; (i) *Rule 11 of the Federal Rules of Civil Procedure* (ii) *the common law tort of abuse of process* and (iii) *the federal courts' inherent authority to protect the integrity of the judicial process*.²⁹⁸ Under each of these doctrines, a plaintiff's subjective intent is determinative.

The elements of a valid cause of action of *the common law tort of abuse of process*²⁹⁹ is generally defined as the malicious and deliberate misuse or perversion of regularly issued court process not justified by the underlying legal action. In such cases, sanctions may be imposed upon a person who is interested only in accomplishing some improper purpose that is collateral to the proper object of the process and that offends justice.³⁰⁰

Rule 11 requires an attorney or party to certify that a pleading, motion, or other paper filed is 'not interposed for any improper purpose, such as to harass or cause unnecessary delay or needless increase in the cost of litigation'.³⁰¹ While *Rule 11's* reach may be somewhat limited in the sense that a well grounded initial complaint cannot, of itself, violate the purpose element and be sanctioned,³⁰² it is nevertheless thought that 'if a court finds that a motion or paper, other than a complaint, is filed in the context of a persistent pattern of clearly abusive litigation activity, it will be deemed to have been filed for an improper purpose and sanctionable even if it is not frivolous'.³⁰³

Finally, a federal court always has *the inherent authority* to assess attorney's fees when a party has acted in bad faith, vexatiously, wantonly, or for oppressive reasons³⁰⁴ – although, of course – such inherent powers must be exercised with restraint and discretion.³⁰⁵

²⁹⁸ Charles C. Hsieh, 'Professional Real Estate: The Line between Patent and Antitrust', Harvard Journal of Law & Technology, Volume 7, Number 1 Fall 1993, 173, pp. 183-4, available at <http://jolt.law.harvard.edu/articles/pdf/v07/07HarvJLTech173.pdf>.

²⁹⁹ See e.g. Joseph B. Maher, 'Survival of the Common Law Abuse of Process Tort in the Face of a Noerr-Pennington Defense', *The University of Chicago Law Review*, Vol. 65, No. 2 (Spring, 1998), pp. 627-652.

³⁰⁰ *Abuse of process* is to be distinguished from *malicious prosecution*, another type of tort that involves misuse of the public right of access to the courts.

³⁰¹ Fed. R. Civ. P. 11.

³⁰² See the Ninth Circuit in *Zaldviar v. City of Los Angeles* 780 F.2d 823 (9th Cir. 1986).

³⁰³ *Aetna Life Ins. Co. v. Alla Medical Servs.*, 855 F.2d 1470, 1476 (9th Cir. 1988). See Hsieh, p. 184-5, fn. 76.

NB: *Frivolous litigation* is a legal claim or defense presented even though the party and the party's legal counsel had reason to know that the claim or defense had no merit. A claim or defense may be frivolous because it had no underlying justification in fact, or because it was not presented with an argument for a reasonable extension or reinterpretation of the law, or because laws are in place unequivocally prohibiting such a claim.

³⁰⁴ *Alyeska Pipeline Serv. Co. v. Wilderness Soc.y*, 421 U.S. 240, 258-59 (1975) (citation omitted) See also *Chambers v. NASCO*, 111 S.Ct. 2123 (1991); *Hall v. Cole*, 412U.S. 1, 5 (1973).

³⁰⁵ See *Roadways Express, Inc. v. Piper*, 447 U.S. 752, 764 (1980).

6.2.2 Abuse of Process in the EC Legal System

Abuse of process rules exist in most Member States of the Community, but vary greatly in scope and reach. As the issue is a matter of national concern, abuse of process is dealt with very differently in each Member State. Whereas e.g. Swedish courts, apart from being able to strike out obviously unfounded actions and to require a party who has instituted unnecessary legal proceedings to bear the costs,³⁰⁶ lack specific remedies that target such abuses, their UK counterparts have a well developed system of rules and remedies targeting ‘vexatious litigants’ to fall back upon.³⁰⁷

Under the UK common law tort of abuse of process, even an action, which is well founded, can amount to an abuse, provided that it is brought for the predominant purpose of using the legal process for something other than that which it was designed.³⁰⁸ The UK remedies are to be found in the Civil Procedure Rules as well as in the various IP laws. Under *Section 42 of the Supreme Court Act 1981* a High Court may, if satisfied that any person has habitually and persistently and without any reasonable ground instituted vexatious civil proceedings, make an order restricting the right of access to the courts. Also, the IP laws contain explicit rules that prohibit abuse of process through the use of IPRs. In relation to registrable rights such as patents, these rules include groundless threats of such actions. In particular, *Section 70 of the UK Patents Act 1977* provides remedies for unjustified threats of proceedings for patent infringement. A person aggrieved by the threats may bring proceedings in the court against the person making the threats, claiming relief in the form of a declaration to the effect that the threats are unjustifiable, an injunction or interdict against the continuance of the threats, or damages in respect of any loss which the plaintiff or pursuer has sustained by the threats.³⁰⁹

6.3 Monopolization through IP Enforcement in the US

Although patents grant certain rights that restrain competitors, antitrust law defines the limits of permissible anticompetitive behaviour. The Supreme

³⁰⁶ An ‘obviously unfounded’ civil suit may be struck out by the court under RB 42 kap. 2-4§§. Moreover, the rules on the distribution of costs give the courts the power to require a party who has instituted ‘unnecessary proceedings’ to bear the costs of the legal proceedings under RB 18 kap. 3§ 1st. Similarly, the German system has chosen costs rules to deter frivolous actions and defences. The general rule in civil procedure is that the losing party bears the costs (court fees, lawyers’ fees, witness and expert expenses) of the opposing party. Such cost orders are viewed as a sufficient disincentive against pursuing frivolous claims, actions or defences.

³⁰⁷ See Nettleton and Cordery, pp. 52-54. See also Hughes Jean, ‘Trademarks Unjustified Threats’, *European Intellectual Property Review*, Vol. 22, No. 8, 2000, pp. N116-117. For a comprehensive analysis of the abuse of process, see W. Wells ‘*The Abuse of Process*’ (1985) 102 L.Q.R.

³⁰⁸ Compare Steven Preece, p. 122.

³⁰⁹ *Id.*

Court made this point clear in the landmark 1942 case of *Morton Salt*.³¹⁰ Even though a 'patent operates to create and grant to the patentee an exclusive right to make, use and vend the particular device described and claimed in the patent', the Court held that a patent 'affords no immunity for a monopoly not within the grant, and the use of it to suppress competition [...] may deprive the patentee of the aid of a court of equity to restrain an alleged infringement by one who is a competitor'.³¹¹ However, exactly where the line of demarcation between a lawful assertion of IPRs and an antitrust violation should be drawn has been a subject of much confusion, especially in the context of IPR enforcement.³¹²

An illustrative example of the US approach can nevertheless be seen in the *CSU litigation*.³¹³ Here, Xerox Corporation had refused to sell patented parts, copyrighted manuals, and copyrighted software to CSU and other independent service organizations (ISOs),³¹⁴ which caused CSU to sue Xerox for a Sherman Act Section 2 violation. Xerox counterclaimed for patent infringement.³¹⁵ In determining the outcome of whether Xerox's patents provided Xerox with immunity in relation to the antitrust laws, the Federal Circuit noted from its prior case law that 'a patent owner who brings suit to enforce the statutory right to exclude others from making, using, or selling the claimed invention is exempt from the antitrust laws, even though such a suit may have an anticompetitive effect, unless the infringement defendant proves one of two conditions. First, he may prove that the asserted patent was obtained through knowing and wilful *fraud* [...] or he may demonstrate that the infringement suit was a mere *sham* to cover what is actually no more than an attempt to interfere directly with the business relationships of a competitor'.³¹⁶ The Federal Circuit held, that '[i]n the absence of any indication of [...] fraud in the Patent and Trademark Office, or sham litigation, the patent holder may enforce the statutory right to exclude others from making, using, or selling the claimed invention free from liability under the antitrust laws. We therefore will not inquire into his subjective motivation for exerting his statutory rights, even though his refusal to sell or license his patented invention may have an anticompetitive effect, so long as that anticompetitive effect is not illegally extended beyond the statutory patent grant.'³¹⁷

This very well reflects the traditional approach of ensuring that antitrust immunity is conferred upon firms, including monopolists, that petition

³¹⁰ *Morton Salt Co. v. G.S. Suppiger Co.*, 314 U.S. 488 (1942).

³¹¹ *Morton Salt*, 490-91.

³¹² Compare Hsieh, p. 173.

³¹³ *In re Independent Service Organizations Antitrust Litigation (CSU)* 203 F.3d 1322, 1325 (Fed. Cir. 2000).

³¹⁴ *Id.* at 1324.

³¹⁵ *Id.* Xerox also had counterclaims for copyright infringement as well as contesting and defending against CSU's claims and defenses.

³¹⁶ *CSU*, 203 F.3d at 1326 (emphasis added).

³¹⁷ *Id.* at 1327-28. On the facts of the case, the Federal Circuit concluded that Xerox did not violate any antitrust provisions by relying on its patent rights to refuse to sell or license its patented work to CSU and other ISOs.

government through lobbying, administrative procedures or litigation.³¹⁸ The general rule is therefore that enforcement of IPRs will not lead to an antitrust violation. However, there are certain exceptions to this rule.³¹⁹ Litigation in which the governmental or judicial process is used as an anti-competitive weapon, is not protected. Rather, such anti-competitive litigation violates Section 2 of the Sherman Act under three main theories. Under each theory, harassing patent infringement actions may be caught by antitrust law. Though not always successful, Section 2 claims based on anti-competitive litigation are becoming increasingly common.³²⁰

6.3.1 Noerr-Pennington Immunity

At the very intersection between the Sherman Act and the First Amendment lies *Noerr-Pennington* immunity. The immunity doctrine, based upon the right to petition the government in the First Amendment, was laid out in three Supreme Court cases.

In the first decision, *Noerr*, the Court held that ‘no violation of the [Sherman] Act can be predicated upon mere attempts to influence the passage or enforcement of laws.’³²¹ Consequently, railroads’ publicity and *lobbying efforts to obtain favourable state legislation* that would destroy their motor trucking competitors were immune from antitrust attack. Noting that ‘[t]he right of petition is one of the freedoms protected by the Bills of Rights’, the Court refused to apply antitrust analysis to the railroads’ activities ‘insofar as those activities comprise mere solicitation of governmental action with respect to the passage and enforcement of laws.’³²² Nevertheless, the Court concluded with the important statement that ‘[t]here may be situations in which a publicity campaign, ostensibly directed toward influencing governmental action, is actually nothing more than an attempt to interfere directly with the business relationships of a competitor’. In such exceptional circumstances an ‘application of the Sherman Act would be justified.’³²³

The immunity granted under *Noerr* soon evolved beyond the limited legislative arena. In *Pennington*, the doctrine was applied to protect efforts to influence an *administrative proceeding*.³²⁴ The Supreme Court ruled that ‘[j]oint efforts to influence public officials do not violate the antitrust laws even though intended to eliminate competition. Such conduct is not illegal,

³¹⁸ *E.R.R. v. Noerr Motor Freight*, 365 U.S. 127, 135-37, 145 (1961); *United Mine Workers v. Pennington*, 381 U.S. 657, 671-72 (1965). See the *Noerr-Pennington Doctrine* below.

³¹⁹ Balto & Wolman, p. 74.

³²⁰ See Meurer, p. 540; Davies, Leburn & Stargard, ‘*Seeking the Right Balance to Maintain a Free Market*’, <http://howrey.com/docs/seekingtherightbalance.pdf>, p. 4.

³²¹ *Eastern Railroad Presidents Conference v. Noerr Motor Freight Inc.*, 365 U.S. 127 (1961).

³²² *Id.* at 138.

³²³ *Id.* at 144. In other words, the focus was on whether the purpose of the petition was to directly eliminate competition rather than to obtain favourable government action. Lobbying to obtain government action the result of which was to restrain trade was permissible; lobbying without expectation of government action, but with the intent to harm competition, was not. See S.W. O’Donnell, pp. 7-9.

³²⁴ *United Mine Workers v. Pennington*, 381 U.S. 657 (1965).

either standing alone or as part of a broader scheme itself violative of the Sherman Act.³²⁵

Finally, in *California Motor*, the Court extended the application of the immunity doctrine to a *judicial proceeding*.³²⁶

6.3.2 The Walker Process Doctrine

As noted above however, there are exceptions to the *Noerr-Pennington* immunity. The first applies only to patent infringement suits where the antitrust plaintiff can show that the patent holder fraudulently obtained his patent and that he would not have obtained it but for the fraud.³²⁷

In the landmark case of *Walker Process Equipment*,³²⁸ the Supreme Court held that when a company obtains a patent by committing *fraud* on the US PTO and then attempts to *enforce* that patent on its competitor, this purposeful anticompetitive conduct may be the basis of an antitrust action under Section 2 of the Sherman Act.³²⁹ The doctrine has since been developed further in a number of important circuit court cases.³³⁰ As the doctrine now stands, the antitrust plaintiff must show:

(i) that the patent owner acquired the patent by means of either fraudulent misrepresentation or a fraudulent omission of pertinent information, evidencing a clear intent to deceive the patent examiner,³³¹

(ii) that this caused the PTO to issue an invalid patent that would not have been granted absent the fraudulent conduct,³³² and

(iii) that the patentee was aware of the fraud when bringing the suit to enforce its patent.³³³

(iv) Lastly, the other elements for a Section 2 offence must be present.³³⁴

Most often *Walker Process* claims arise as counterclaims in patent infringement litigation. However, a Section 2 violation can also result where the patent was not secured by fraud but the patentee came to know that the patent was invalid and nevertheless pursued the infringement action.³³⁵

³²⁵ *Id.* at 670.

³²⁶ *California Motor Transport Co. v. Trucking Unlimited*, 404 U.S. 508 (1972).

³²⁷ See Meurer, pp. 538-540.

³²⁸ *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.* 382 U.S. 172 (1965).

³²⁹ *Id.* at 174. Consequently, the maintenance and enforcement of the fraudulently obtained patent can also be subject to a treble damages claim by an injured party under s.4 of the Clayton Act (at 176-77).

³³⁰ See e.g. *Cataphote Corp. v. DeSoto Chemical Coatings, Inc.*, 450 F.2d 769, 771-73 (9th Cir. 1971); *Monsanto Co. v. Rohm & Haas Co.*, 456 F.2d 592, 599-600 (3d Cir. 1972); *Litton Indus. Prods., Inc. v. Solid State Sys. Corp.*, 755 F.2d 158, 166 (Fed. Cir. 1985).

³³¹ See *Nobelpharma AB v. Implant Innovations, Inc.*, 129 F.3d 1463 (Fed. Cir. 1997), rev'd, 141 F.3d 1059, 1068-70 (Fed. Cir. 1998).

³³² *Litton*, 755 F.2d at 166; *Nobelpharma*, 141 F.3d. at 1071.

³³³ See Gunther & Breuvar, fn. 15.

³³⁴ Apart from proof of power in the relevant market, that means that injury must be a proximate result of the enforcement actions. This means that the plaintiff must at minimum have been ready, willing, and able to manufacture the patented subject matter. See *Indium Corp. of America v. Semi-Alloys, Inc.*, 611 F. Supp. 379, 385 (N.D.N.Y. 1985), aff'd, 781 F.2d 879 (Fed. Cir. 1985).

³³⁵ See *Handgards, Inc. v. Ethicon, Inc.*, 601 F.2d 986, 994 (9th Cir. 1979).

An illustrating and recent example of a *Walker Process* type fraud against a government body is the settlement in October 2005 between the FTC, Akzo Nobel, and its subsidiary Organon. More specifically, this *Akzo Nobel-Organon* settlement concerned ‘fraudulent misrepresentation’ to the US Food and Drug Administration (FDA) to delay generic entry. Charges against Organon involved false representations to the FDA about the claims of a patent listed on the FDA's Orange Book,³³⁶ so as to delay by about eight months the introduction of generic competition to its antidepressant, Remeron. Under the settlement, Organon agreed to pay tens of millions of dollars in damages and to comply with strong injunctive terms barring future anti-competitive conduct.³³⁷

6.3.3 The Sham Litigation Doctrine

The second exception concerns *sham litigation*, including sham IP litigation, and is based on a showing that the antitrust defendant (i.e. the IP plaintiff) knew that his infringement claim was objectively baseless.³³⁸

In *California Motor*, the Court stated that antitrust laws may apply where the litigation ‘is a mere sham to cover what is actually nothing more than an attempt to interfere directly with the business relationships of a competitor and the application of the Sherman Act.’³³⁹ While the Court noted that a pattern of baseless, repetitive claims may be considered a ‘sham’, it also acknowledged that the boundary between sham and legitimate conduct may be ‘a difficult line to discern and draw.’³⁴⁰ Since the Supreme Court did not even attempt to remedy this obscurity, lower courts were left with the difficult task – something that was to have a negative impact on consistency and legal certainty.³⁴¹

³³⁶ The FDA's *Orange Book* (officially entitled ‘*Approved Drug Products with Therapeutic Equivalence Evaluations*’) lists all approved drugs and related patents for each drug. The FDA obtains this information from New Drug Applications (NDAs), which must include information on any patent covering the drug, any method of using the drug for treatment of disease, or any method of delivery of the drug, for which a claim of patent infringement could reasonably be asserted against an unauthorized party. See Thomas Leary, ‘*Antitrust Issues in the Settlement of Pharmaceutical Patent Disputes – Part II*’, 1/24/02, available at <http://www.ftc.gov/speeches/leary/learypharmaceuticalsettlement.htm>, visited on June 20, 2007. See also Gunther & Breuvar, pp. 671-72 for a brief preliminary overview of the US drug approval process (the Hatch-Watchman drug approval process).

³³⁷ See www.ftc.gov/opa/2004/10/organon.htm, visited on June 20, 2007. See also Eccles & Ferla, pp. 4-5.

³³⁸ See Meurer, pp. 538-540.

³³⁹ *California Motor Transport Co. v. Trucking Unlimited*, 404 U.S. 508 (1972), at 510-11.

³⁴⁰ *Id.* at 513.

³⁴¹ In particular, there was a dispute among the lower courts as to ‘the proper mix of subjective and objective criteria in determining whether specific litigation should be entitled to Noerr-Pennington immunity. While some circuits held that litigation which raised a legal issue of genuine substance could never be a sham, others would confer such litigation only a presumption that it was not a sham, leaving the issue open to rebuttal by evidence that the suit was brought purely to cause inconvenience, harass, or harm competitors, and not for the end of obtaining favourable judicial relief. See Neal R. Scholl & Shepard Goldfein, ‘*The Supreme Court and the Sham Exception*’, N.Y. Law Journal, May 18, 1993, at 3. See also Hsieh, pp. 173-76.

Faced with inconsistent and sometimes contradicting decisions, the Supreme Court in *Professional Real Estate (PRE)*³⁴² sought to settle the uncertainty once and for all. The case involved a copyright infringement action brought by Columbia Pictures against PRE, which caused PRE to counterclaim that Columbia Pictures' infringement suit was a violation of the Sherman Act. In particular, PRE claimed that the copyright infringement action was a *sham*, brought with the intent to monopolise and restrain trade.³⁴³ Columbia Pictures argued that the suit was no 'sham' and that it was therefore entitled to *Noerr-Pennington immunity* for petitioning the government.³⁴⁴

Having noted that 'the sham exception contains an indispensable objective component', the Supreme Court adopted a two-part test for when a lawsuit loses antitrust immunity and can be termed a 'sham';

(i) First, the suit must be *objectively baseless* in the sense that no reasonable litigant could realistically expect success on its merits.

(ii) Only if the challenged litigation is objectively merit-less, 'may a court [then] examine the litigant's *subjective motivation*.'³⁴⁵ Here, focus should be on whether the baseless lawsuit conceals an 'attempt to interfere directly with the business relationship of a competitor'³⁴⁶ through the 'use [of] the governmental process – as opposed to the outcome of that process – as an anticompetitive weapon'.³⁴⁷

Upon an application of the two-part test to the facts, the Supreme Court concluded that Columbia Pictures had had 'probable cause' in bringing its copyright infringement action. Consequently, the objective component was satisfied and a finding of 'sham litigation' precluded.³⁴⁸

In *Nobelpharma*,³⁴⁹ the Federal Circuit confirmed that the *enforcement of a patent for sham purposes* is a type of anti-competitive act, which is separate and independent from the *enforcement of a patent obtained by Walker Process fraud*.³⁵⁰

As the *sham litigation doctrine* stands today, the objectively baseless standard is thought to apply to the lawsuit as a whole, with the consequence that a lawsuit will not be held to be a sham if some causes of action are baseless but others are well founded.³⁵¹ Sham litigation suits can allege either that the patent holder knew that their relevant patent was invalid *or* that the patent holder knew that the patent, while valid, was not being infringed. In addition, sham litigation counterclaims are frequently filed in patent infringement suits.³⁵²

³⁴² *Professional Real Estate Invs., Inc v. Columbia Pictures Inds., Inc.*, 113 S.Ct 1920 (1993).

³⁴³ *Columbia Pictures Inds., Inc. v. Professional Real Estate Invs., Inc.*, 944 F.2d 1525, 1527 (9th Cir. 1991)

³⁴⁴ *PRE Invs., Inc. v. Columbia Pictures Inds., Inc.*, 113 S. Ct. 1920, 1924 (1993).

³⁴⁵ 113 S.Ct at 1928 (emphasis added).

³⁴⁶ 113 S.Ct. at 1929 (quoting Noerr).

³⁴⁷ *City of Columbia v. Omni Outdoor Advert., Inc.*, 499 U.S. 365, 380 (1991).

³⁴⁸ 113 S.Ct at 1929-30. See Hsieh, pp. 173-79.

³⁴⁹ *Nobelpharma AB v Implant Innovations, Inc.* (141 F.3d 1059 (Fed. Cir. 1998)).

³⁵⁰ See Gunther & Breuvert, fn. 16.

³⁵¹ See *Eden Hannon & Co. v. Sumitomo Trust & Banking Co.*, 914 F.2d 556, 565 (4th Cir. 1990) and *Matsushita Elecs. Corp. v. Loral Corp.*, 974 F. Supp. 345, 357 n. 20 (S.D.N.Y. 1997).

³⁵² See Balto & Wolman, pp. 75-6.

A recent example of the application of both the *Sham doctrine* and the *Walker Process doctrine* is the *In re Buspirone Patent Litigation* from 2002.³⁵³ This involved six antitrust complaints brought by states, generic drug producers and purchasers as well as consumer organizations against Bristol-Myers Squib (BMS) for unlawfully maintaining its monopoly for buspirone-based drug products. The plaintiffs alleged, inter alia, that BMS, in violation of Section 2 of the Sherman Act, unlawfully had maintained its monopoly by improperly listing a patent in the FDA's Orange Book of patents.³⁵⁴ BMS moved to dismiss the claims on *Noerr-Pennington* and patent immunity grounds.³⁵⁵ These motions were denied by the court.³⁵⁶ Since the government's role in the listing of a patent in the Orange Book was only ministerial, it did not, in the court's view, constitute petitioning under *Noerr-Pennington*.³⁵⁷ Rather, the listings were held to be fraudulent under *Walker Process doctrine*.³⁵⁸ Moreover, the court held that the subsequent patent litigation arose from misrepresentations in the process and was therefore baseless and a '*sham*'.³⁵⁹

In applying the *PRE* definition of sham litigation and the objective test, the district court found that no reasonable litigant could have expected success on the merits of BMS's interpretation of the patent claims.³⁶⁰ According to the court this was 'not a case in which there are occasional places in which [BMS had] mischaracterized or mistaken the relevant issues or legal standards. It [was] a case where [BMS had] repeatedly argued for a position that require[d] establishing a number of claims, each of which ha[d] no basis.'³⁶¹ Consequently, BMS's conduct was 'objectively baseless'.³⁶²

The *Buspirone decision* is significant for several reasons. First of all it suggests that a submission to the government is not petitioning, and that it is therefore not immune under *Noerr-Pennington*. Secondly, it is the first decision to apply the *Walker Process doctrine* outside the context of a filing with the PTO. Lastly, it makes clear that inconsistent positions taken by a patent holder may serve as a basis for a finding of an objectively merit-less claim and a *sham litigation*.³⁶³

Following these events in 2002, the FTC in 2003 then alleged in a complaint that BMS had engaged in a decade-long pattern of anticompetitive conduct in order to delay generic competition to the three drugs *BuSpar*, *Taxol* and *Platinol*.³⁶⁴ More specifically, the FTC complaint alleged that BMS wilfully

³⁵³ *In re Buspirone Patent Litigation*, 185 F. Supp. 2d 363 (S.D.N.Y. 2002).

³⁵⁴ *Buspirone*, 185 F. Supp. 2d at 366.

³⁵⁵ *Id.* at 367-69.

³⁵⁶ *Id.* at 380.

³⁵⁷ *Id.* at 369-73.

³⁵⁸ *Id.* at 373-75.

³⁵⁹ *Id.* at 375-76. Compare the *AstraZeneca* decision below.

³⁶⁰ *Id.*

³⁶¹ *Id.* (citing *California Motor Transport Co. v. Trucking Unlimited*, 404 U.S. 508, 513 (1972) for the proposition that objective baselessness can be established by a 'pattern of baseless, repetitive claims').

³⁶² *Id.*

³⁶³ See Balto & Evans, *supra* n. 432, at 38.

³⁶⁴ Of particular interest for the purposes of the present thesis are the FTC allegations in relation to *Buspar*; the FTC alleged that BMS engaged in monopolization of the drug in

maintained its monopoly over each of the three products by abusing government regulatory processes by, amongst other things, improperly listing patents for all three drugs in the Orange Book in order to obtain unwarranted 30-month stays on FDA approval of generic competitors.³⁶⁵

According to the FTC, BMS had thus violated the anti-monopolization provision of Section 5 of the FTC Act³⁶⁶ by intentionally misleading the FDA about the scope, validity, and enforceability of these patents.³⁶⁷ The FTC concluded that *Noerr-Pennington immunity* did not apply to Orange Book listings because they do not constitute petitioning. In addition, the FTC stated that the filings fell outside of the *Noerr-Pennington* exception because they involved knowing and material misrepresentations.³⁶⁸

In re Bristol-Myers Squibb the FTC approved the issuance of a final Consent Order against BMS.³⁶⁹ This eliminated BMS's ability to obtain a 30-month stay on later-listed patents (i.e. patents listed in the Orange Book after a generic manufacturer has sought FDA approval for a competing generic version). The Order also barred a 30-month stay in cases where BMS had engaged in misconduct in connection with obtaining and listing the patent. The relevant misconduct included (i) inequitable actions before the PTO in obtaining the patent, (ii) making false or misleading statements to the FDA in connection with listing the patent, and (iii) providing patent information to the FDA that was inconsistent with information provided to the PTO.³⁷⁰

The *BMS decision* is significant because it represents the first Orange Book enforcement action brought by the FTC against a brand name drug company, as a result of which it is now clear that improper Orange Book listings could constitute a violation of US antitrust laws.³⁷¹

violation of Section 5 of the FTC Act by, among other practices: (i) providing false and misleading information to the FDA in order to cause the FDA to list the patent in the Orange Book and withhold approval for generic bupirone products; (ii) wrongfully submitting the patent for Orange Book listing without a reasonable good faith belief that the patent met the statutory listing requirements; and (iii) initiating and maintaining objectively baseless lawsuits against generic bupirone competitors, without regard to the merits of these lawsuits.

³⁶⁵ See *In the Matter of Bristol-Myers Squibb*, FTC Docket No. C-4076 (complaint) (2003), available at <http://www.ftc.gov/os/2003/04/bristolmyerssquibbcmp.pdf>. Visited on June 20, 2007.

³⁶⁶ That is, the acts unreasonably restrained trade in violation of Section 5 of the FTA, 15 U.S.C. § 45.

³⁶⁷ *In the Matter of Bristol-Myers Squibb* at 24-26.

³⁶⁸ *Id.* at 24. Moreover, the complaint alleged that BMS had entered into anti-competitive settlements contrary to Section 5 of the FTC Act (*Id.* at 5-7, 18-20, 24, 26).

³⁶⁹ See *In the Matter of Bristol-Myers Squibb*, FTC Docket No. C-4076 (decision and order) (2003), available at <http://www.ftc.gov/os/2003/04/bristolmyerssquibbdo.pdf>. Visited on June 20, 2007.

³⁷⁰ *In the Matter of Bristol-Myers Squibb* (decision and order) at 6-7. See Balto & Wolman, pp. 76-79; See also Gunther & Breuvar, pp. 674-676.

³⁷¹ *Id.* Compare the *AstraZeneca* decision below.

6.3.4 Infringement Suits as Part of Scheme to Monopolize

Finally, a third category of exception to the general rule that antitrust enforcement will not lead to antitrust liability was established in *Kobe*.³⁷² Here, it was established that a patent holder may incur antitrust liability when bringing a patent infringement suit even without bad faith where the lawsuit is part of a larger scheme to monopolise that would violate Section 2 of the Sherman Act.³⁷³

In *Kobe*, such a scheme was found to exist by looking at *the infringement suits in combination with other activities*. These involved acquisitions of all material patents in the industry, the signing of covenants not to compete as well as threatened suits against companies trading with the alleged patent infringers.³⁷⁴ However, as the court noted, in isolation from the other activities, the infringement suits themselves would not have been unlawful.³⁷⁵

6.4 Abuse of a Dominant Position through IP Enforcement in the EC

Some examples of national rules on abuse of process were dealt with above. As to the Community level, EC competition law concerns in this context may arise only where it can be argued that a dominant undertaking's abuse of process has negative implications on competition on the common market.³⁷⁶ More specifically, vexatious litigation issues – though rare – have arisen in the context of Article 82 and thus in situations involving an abuse of a dominant position.³⁷⁷

6.4.1 Background – BBI / Boosey & Hawkes

That it may be an infringement of Article 82 for a dominant undertaking to pursue legal proceedings against a competitor was first suggested in *BBI/Boosey & Hawkes*.³⁷⁸ Here, a dominant firm had allegedly initiated groundless harassing copyright infringement actions against a competitor in order to prevent it from entering the dominant firm's market.³⁷⁹ According

³⁷² *Kobe, Inc. v. Dempsey Pump Corp.*, 198 F.2d 416 (10th Cir. 1952).

³⁷³ See *Kobe* at 422-24; *Dairy Foods, Inc. v. Dairy Maid Prods. Coop.*, 297 F.2d 805, 809 (7th Cir. 1961); *Rex Chainbelt, Inc. v. Harco Prods., Inc.*, 512 F.2d 993, 1004-05 (9th Cir. 1975).

³⁷⁴ *Kobe* at 424-25.

³⁷⁵ *Id.* at 425. See Balto & Wolman, p. 79.

³⁷⁶ Note that the anti-competitive considerations of such an action is entirely *sui generis* from the existing abuse of process doctrines illustrated above. 'Two very different mischiefs are at issue.' See Steven Preece, pp. 120-21.

³⁷⁷ That 'abuse of process' is not to be found in Article 82 exemplification of abuses is not an issue, as the list is not exhaustive. See above.

³⁷⁸ *BBI/Boosey & Hawkes* [1987] OJ L286/36. See also Jones & Sufrin p. 423.

³⁷⁹ See para. 9 of the decision where the most significant allegations were summarised. Under point (a) it was stated 'that B&H had pursued unjustified litigation in the United

to the complainant's submission, this conduct was abusive. However, as the Commission decision merely concerned the imposition of interim measures, the Commission did not pursue these allegations. Consequently, the question as to whether vexatious litigation could be an abuse was left unanswered.³⁸⁰ Nevertheless, this does not prevent one from arguing that there is nothing in the decision that suggested that the Commission did *not* consider the harassing actions as an Article 82 abuse.

6.4.2 Decca Navigator System

A somewhat clearer example is *Decca Navigator System*³⁸¹. The case concerned the DNS, an international radio navigation system invented by Decca and operated throughout the world for navigation mainly at sea. It consists of transmission of signals by land-based stations and devices, which receive these signals (receivers). When the basic patents which prevented third parties from manufacturing receivers legally without a licence expired in the mid-1960's, Decca sought other ways of defending its strong market position. Through a series of agreements, Decca licensed the right to the *signals* to which it claimed to have copyright and shared the market for *receivers* with competitors. However, Decca was then informed by Delta Marine of its intentions to import and to market a DNS-compatible, non-Decca receiver in the UK. Decca responded that such actions would infringe its copyright relating to the DNS and that it would take legal actions to prevent Delta Marine from realising its plans. When they nevertheless did, Decca brought legal proceedings against Delta Marine and other companies importing the receiver in a number of countries, in most cases for 'unfair competition'.³⁸²

Delta Marine complained to the Commission about Decca's behaviour. In its decision, the Commission cited an internal telex, based on information from Decca, stating that 'Decca's tactics towards [its competitors] is to exhaust them by cases in eight countries at a time.' Moreover, the information revealed that Decca pursued 'the consistent policy of asking a long series of questions in each single case, questions which demand an answer from [the competitors]', and that Decca's aim was 'to fatigue [them] on legal questions rather than beat them on legal ground'.³⁸³

The commission based its finding of abuse of Decca's dominant position on the conduct around the conclusion of the agreements as well as on the changes in signals made for the purpose of impeding the functioning of

Kingdom against BBI for breach of copyright which it (B&H) eventually had to abandon but which had the effect of imposing a heavy financial burden on the applicants and of delaying the launching of the new range at a critical time'.

³⁸⁰ See para. 11 of the decision: 'The present Decision is not directly concerned with the allegations of vexatious litigation and other harassing tactics but only with the closure of accounts and refusals to supply'.

³⁸¹ *Decca Navigator System* OJ [1989] L 43/27.

³⁸² Decca argued that the competing companies were free-riding on the DNS financed by Decca. Both Danish and Dutch courts rejected that claim and considered that Decca's transmission signals could be used legally by anybody in possession of an appropriate receiver. *Id* para. 48.

³⁸³ *Id* para. 50.

competing receivers. By that conduct, Decca had aimed at protecting the monopoly position it enjoyed for commercial receivers and had intended to exclude, obstruct and coerce competitors.³⁸⁴

As to the copyrights claimed by Decca, the Commission argued that it was not necessary to ascertain whether those really existed. For, in the Commission's words, 'the object of the agreements had been to allocate the markets' and 'the substance of the copyright alleged did not justify an agreement containing such far-reaching restrictions of competition. The Community system of competition does not allow an improper use of rights under national copyright laws which frustrate Community competition law.'³⁸⁵

Despite the fact that the Commission decision does not explicitly comment on Decca's procedural strategy and the question whether such behaviour could be reconciled with Article 82, it appears that the Commission regarded the procedures brought, or the threats thereof, as part of the total picture, i.e. as part of the strategy amounting to an abuse of a dominant position. According to some commentators, the decision thus represents an example of a situation where procedural measures may amount to an abuse under Article 82.³⁸⁶ Clear is however, that other elements of Decca's behaviour offered enough legal ground for the decision and that the Commission thus did not have to engage in the more sensitive act of restricting the right of access to the courts.³⁸⁷ The value of the decision in this context is therefore limited.

6.4.3 ITT Promedia v. Commission

Of more value in this respect is the later judgement in *ITT Promedia*.³⁸⁸ The case concerned an appeal against the decision by the Commission to reject a complaint made by Promedia against Belgacom, the dominant (and former monopoly) telephone operator in Belgium. Promedia had previously enjoyed the exclusive right to publish telephone directories in Belgium, which it had been granted by RTT, the predecessor to Belgacom. However, as discussions to conclude a renewal of this concession broke down, a sequence of lawsuits and counter-claims between the two parties followed.³⁸⁹

Promedia complained to the Commission about Belgacom's conduct in 1994. It alleged inter alia that Belgacom had abused its dominant position by initiating *vexatious litigation* against it before the Belgian courts.³⁹⁰ That complaint was rejected in a Commission decision in 1996 (hereafter referred

³⁸⁴ Id paras. 97-98.

³⁸⁵ Id para. 104. Compare above.

³⁸⁶ Lundgard Hansen Kim, Kjøbye Lars, Saugmandsgaard Øe Henrik, '*EU-konkurrenceretten*', Köpenhamn, 1998, s. 195.

³⁸⁷ Compare the *AstraZeneca* decision below.

³⁸⁸ Case T-111/96 *ITT Promedia NV v. Commission* [1998] ECR II-2937.

³⁸⁹ Steven Preece, p. 119.

³⁹⁰ Complaint IV/35.268. One of the other elements of the complaint, that Belgacom had infringed Article 82 by imposing excessive prices for access to subscriber data, ultimately was the subject of a settlement between Belgacom and the Commission in April 1997.

to as ‘the contested decision’).³⁹¹ While the Commission conceded that the bringing of litigation by a dominant firm could infringe Article 82, the abuse was not made out in the instant case.

Such an abuse could, in the Commission’s view, only ever be the case provided two cumulative criteria were fulfilled – namely where a dominant undertaking brought an action:

- (i) which could not reasonably be considered as an attempt to establish its rights and could therefore only serve to harass the opposite party *and*
- (ii) which was conceived in the framework of a plan whose goal was to eliminate competition.³⁹²

The Commission’s test – based on the human right of access to the courts – was thus not whether the right claimed exists, but whether the dominant undertaking may reasonably consider that it does.³⁹³ On the basis of the evidence put forward, the Commission considered that Belgacom's legal actions, which included counterclaims and lawsuits of its own initiation, could reasonably be construed as attempts by that party to establish its legal rights. They could not have been seen as so unreasonable and groundless that they were only serving to harass Promedia.³⁹⁴ Moreover, since two of the actions were actually counterclaims, they could not be viewed as being part of a plan to eliminate competition.³⁹⁵

Promedia sought annulment by the CFI of the Commission's rejection of its complaint.³⁹⁶ It alleged *inter alia* that the Commission's rejection was based upon a manifest error of assessment. Promedia also argued that the Commission had failed to provide an adequately reasoned decision as required by Article 253 EC. However, it did not challenge the Commission's cumulative criteria themselves. Consequently, the CFI stated that it merely had to ‘establish whether the Commission correctly applied the cumulative criterion’ and that ‘there [was] no need for it to rule on the correctness of the criteria chosen by the Commission in the contested decision’.³⁹⁷

The CFI then went on to note that the right to access to the courts was a fundamental right, common to the constitutional regimes of all Member States, and laid down in Articles 6 and 13 of the ECHR.³⁹⁸ Accordingly, the CFI stated that it was only ‘in wholly exceptional circumstances that the fact that legal proceedings are brought is capable of constituting an abuse of a dominant position within the meaning of [Article 82]’.³⁹⁹ Referring to earlier case law, the CFI also stated that such ‘[a]n exception to the principle

³⁹¹ Commission decision by letter of May 21, 1996, rejecting complaint IV/35.268. NB: This Commission decision has not been published (as rejected complaints never are).

³⁹² The contested decision, point 11.

³⁹³ Jones & Sufrin, p. 424.

³⁹⁴ See Case T-111/96 *ITT Promedia NV v. Commission* [1998] ECR II-2937, para. 41.

³⁹⁵ *Id.* para. 42.

³⁹⁶ Case T-111/96 *ITT Promedia NV v. Commission* [1998] ECR II-2937.

³⁹⁷ See paras. 58-59. Despite the fact that the CFI did not rule on the correctness of the criteria, but confined itself to holding that they had been correctly applied ‘[t]he implication of the CFI judgement [...] is that the criteria themselves are correct’, see Jones & Sufrin, pp. 423-24.

³⁹⁸ *Id.* para. 60.

³⁹⁹ *Id.*

of access to the courts, which ensures the rule of law, must be construed and applied strictly, in a manner which does not defeat the application of the general rule'.⁴⁰⁰

In relation to the legal proceedings in question, involving two counter-claims and an action relating to the enforcement of a contractual term relating to IPRs, the CFI concluded that the Commission had applied the first cumulative criterion correctly.⁴⁰¹

As it was clear that the first *counter-claim* could be regarded as the assertion of what Belgacom reasonably considered as its legal rights,⁴⁰² such a proceeding could not be seen solely as an attempt to harass Promedia. The fact that the national law, which gave Belgacom the rights it was asserting, could have infringed EC competition law itself was irrelevant.⁴⁰³ This was also the case in relation to the second counter-claim made by Belgacom.⁴⁰⁴

Arguments alleging that the Commission decision infringed Article 253 EC were also rejected by the CFI.⁴⁰⁵ Contrary to Promedia's assertions, the CFI was of the opinion that the Commission had adequately established why an *action brought by Belgacom relating to a contractual requirement to transfer IPRs* did not fulfil the cumulative criteria.⁴⁰⁶ Under the contractual provisions in question, Promedia was required to transfer to Belgacom 'the licences resulting from patents or similar forms of legal protection granted in relation to works performed or carried out in connection with this agreement, as well as the know-how required' for publication of the directories.⁴⁰⁷ Belgacom had asked the Belgian courts to order a transfer of the trademark rights relating to the directories (as well as related know-how) alleging that this was within its contractual rights. According to the CFI, the Commission's decision stated clearly that Belgacom could reasonably have considered such a transfer to be within the scope of its contractual entitlement. Furthermore, the Commission had noted in its decision that the applicant had not established in fact or law how the action by Belgacom went beyond the scope of the contract.⁴⁰⁸ Hence, there was no deficiency in the Commission's statement of reasons to warrant annulment of the decision in this regard.⁴⁰⁹ Consequently, Promedia was cleared of having abused its dominance by bringing legal proceedings against its customer.⁴¹⁰

⁴⁰⁰ Id para. 61.

⁴⁰¹ Id. para. 115.

⁴⁰² Id. para. 93.

⁴⁰³ Id. para. 94.

⁴⁰⁴ Id. paras 116, 117.

⁴⁰⁵ Id. para. 132.

⁴⁰⁶ Note however that the CFI did hold that a claim for performance of a contractual right by a dominant undertaking could constitute an abuse in certain circumstances, para. 140.

⁴⁰⁷ Id. para. 19

⁴⁰⁸ Id. para. 129.

⁴⁰⁹ Id. para. 132.

⁴¹⁰ This, despite the fact that a Belgian tribunal had held that these proceedings were vexatious or frivolous in character. See Lawrance & Treacy, p. 8.

6.4.4 An EC ‘Vexatious Litigation Doctrine’?

More important than the actual outcome of the case is, however, that the CFI judgment can be seen to have confirmed that *vexatious institution of legal proceedings can constitute an abuse of a dominant position*, albeit only in very limited circumstances where a dominant firm brings an entirely groundless litigation with predatory intent.⁴¹¹

Moreover, it seems that in the absence of criteria formulated by the Community courts, the Commission's cumulative criteria will have to suffice. In any event, the strict Commission criteria seem to reflect the CFI's cautious approach, wary of any careless creation of a new abuse involving the bringing of legal proceedings.⁴¹²

More uncertain is the question whether *vexatious threats* of legal proceedings will be enough to constitute an abuse under Article 82. While *ITT Promedia* does not expressly state that this could be the case, it has been argued that they would, provided all the other criteria for an abuse are satisfied. After all, the anticompetitive economic effect of unilateral conduct by dominant firms is Article 82's primary concern. 'If a dominant undertaking seeks to preserve or strengthen its dominant position on markets by vexatiously threatening to bring, or actually bringing, legal proceedings against its competitors, then this must surely serve to hinder the maintenance of competition still existing on that market. Smaller, weaker competitors will be tempted not to enter or to leave such markets so as to avoid the expense and time of litigation, whatever the merits of the dominant firm's case.'⁴¹³ In addition, it is arguable that the special responsibility imposed upon dominant undertakings must extend to restraining such firms from hindering the maintenance of competition by threatening or commencing lawsuits they know to be groundless.⁴¹⁴

Thus, in *ITT Promedia* the CFI arguably confirmed that predatory litigation by a dominant firm could be an abuse of a dominant position under Article 82 provided, of course, that the other requirements of that article are made out. However, the circumstances under which the abuse will crystallise are strictly limited. For the bringing of legal proceedings to constitute an abuse, they effectively must be predatory – there can be no reasonable cause of action in the sense that the proceedings can only serve to harass the other party – and the action must be part of a plan by the dominant firm to eliminate its competitor.⁴¹⁵

6.4.5 The Legal Position Post *ITT Promedia*

In view of the case law hitherto presented, and in particular with regard to *ITT Promedia*, it may thus seem conceivable that the threatening, or at least bringing, of entirely vexatious proceedings by dominant firms will infringe Article 82 EC, provided that the cumulative criteria are satisfied.

⁴¹¹ Jones & Sufrin, p. 424.

⁴¹² Compare the *AstraZeneca* decision below.

⁴¹³ Steven Preece p. 120.

⁴¹⁴ *Id.*

⁴¹⁵ Steven Preece p. 122.

At the same time, it may seem relevant to question the legitimacy of the criteria set out by the Commission. Since the CFI did not expressly approve those criteria, a counter-argument has often run to the effect that these merely were established in a Commission decision, and thus do not have any binding effect in national law. Arguably, therefore, stronger precedents by the CFI, or ideally the ECJ, on the criteria themselves would be required to settle the matter once and for all. According to this view, *ITT Promedia* did not change the fact that parties in cases involving predatory litigation are kept in a state of legal uncertainty, with the consequence that pleading claims or counter-claims for infringement of Article 82 in national courts remains difficult.⁴¹⁶

Moreover, while some have argued that an Article 82 EC ‘vexatious litigation abuse’ could work alongside and complement the existing causes of action and rules of procedure in national law, others have questioned whether the abuse can be said to have much value in the form it was given in *ITT Promedia*.⁴¹⁷ Considering the strict Commission criteria, the opportunities for alleging such an abuse of dominance would also appear to be much more limited than the existing national doctrines of abuse of process mentioned above.

Irrespective of any practical obstacles, the legal position post *ITT Promedia* must be characterised as one of uncertainty and lack of authoritative precedents. Whether this can be said to have been remedied by the recent *AstraZeneca* decision will be examined in the following section.

⁴¹⁶ Steven Preece, p. 121.

⁴¹⁷ *Id.*

7 AstraZeneca & Its Defence of Losec

Traditionally, the Commission's antitrust enforcement activity in the pharmaceutical sector has focused on removing private obstacles to parallel trade in pharmaceuticals within the Single Market. With the AstraZeneca decision in the Summer of 2005, however, the Commission adopted its first abuse of dominance decision in that sector.⁴¹⁸ In particular, the Decision is the first antitrust case in which the Commission has tackled misuse of patent and drug regulatory approval systems in the pharmaceutical industry on the basis of Article 82 of the EC Treaty, that way blocking or delaying market generic entry.⁴¹⁹ The main findings of this case will be examined below. However, for a proper understanding of the facts of the case it is necessary to first highlight the main features of the pharmaceutical industry.

The *pharmaceutical industry* is a high technology and knowledge intensive industry consisting of two categories of undertakings; The first category is composed of large multinational pharmaceutical undertakings, which are responsible for the majority of the R&D investment, hold the majority of the patents and often dominate the markets for patent protected prescription medicines. For these undertakings, innovation is crucial as competition on this level revolves around developing new or improved medicines. By way of contrast, the second category is composed of a number of often smaller companies, which carry out relatively little R&D of their own, produce off-patent generic medicines or patented medicines under licence and compete mainly in terms of price, service and efficiency.⁴²⁰

The research-based category operates on a high-risk/high-reward basis. Since relatively few of the created chemical entities ever receive marketing approval,⁴²¹ and of these, even fewer are commercially successful, the R&D process in the pharmaceutical industry is indeed an extremely lengthy, costly and risky business. On the other hand, a best selling medicine can be extremely profitable. According to OECD figures, 75 per cent of pharmaceutical company profits come from only 10 per cent of all medicines. Moreover, for some pharmaceutical undertakings, two or three products account for 70 to 80 per cent of their total sales.⁴²²

⁴¹⁸ COMP/37.507 — Generics/Astra Zeneca, 15 .06.2005. See 'AstraZeneca: the first abuse case in the pharmaceutical sector.' EC Competition Policy Newsletter, Number 3 — Autumn 2005, p. 54. See also 'Competition in Pharmaceuticals: the challenges ahead post AstraZeneca',⁴¹⁸ Nadia De Souza, Directorate-General for Competition, unit B-2, EC Competition Policy Newsletter, Number 1 – Spring 2007, p. 39 f.

⁴¹⁹ See Gunther & Breuvert, p. 669; Lawrance & Treacy, p. 7.

⁴²⁰ Gunther & Breuvert, p. 669.

⁴²¹ According to OECD, for every 10,000 products patented, only 100 will reach human trials and only 10 will be marketed. See Biggar, Darryl R., 'Competition and regulation issues in the pharmaceutical industry' (February 6, 2001), Org. for Economic Co-operation & Dev., Best Practice Roundtables in Competition Policy No. 32, p. 91. Available at <http://ssrn.com/abstract=318769> or 10.2139/ssrn.318769. Visited on June 20, 2007.

⁴²² Id. p.91.

The long term prosperity of research based pharmaceutical undertakings thus depends solely on their ability to continually develop superior new medical products and to profitably market these medicines. In this context, strong IP protection is necessary to ensure that companies can recoup their R&D expenditure and be rewarded for their innovative efforts. In particular, as R&D is funded almost exclusively from the profits resulting from the exclusive rights during patents' lifetime, the protection of patents is fundamental. Indeed, when the patent finally expires, the brand name manufacturer can no longer prevent generic manufacturers from producing and selling medicines, which are bio-equivalent to its previously patented medicine. Even though the competitive impact of generic entry will vary upon brand loyalty and price elasticity of the demand, it tends to be significant. As the average price of a generic medicine is typically between 50 and 70 per cent of the average price of the original brand name alternative, it is not unusual for a generic medicine in the US to achieve a 50 per cent market share within a year of patent expiration.⁴²³

For the just mentioned reasons, and in particular to offset the substantial costs and delays associated with obtaining marketing approval, many legal systems (including the European Community and the US) have extended the duration of patent protection in the pharmaceutical industry. However, in order to keep health costs low, they have also adopted policies seeking to encourage competition by generic manufacturers and consumption of lower cost generic medicines by consumers once the patents expire.⁴²⁴

Obviously, these latter policy measures have not been welcomed by the pharmaceutical industry. In their efforts to preserve exclusive rights and profits resulting from their costly patents against aggressively competing generic manufacturers, brand name pharmaceutical undertakings have implemented various practices that have given rise to antitrust scrutiny not only from the US FTC and Courts but – as is evident from the *AstraZeneca* decision – recently also by the European Commission.⁴²⁵

7.1 Background & Arguments

The Commission investigation of AstraZeneca's (AZ's)⁴²⁶ practices with respect to its Losec medicine started in 1999, following a complaint received from a generic group concerning alleged activities undertaken by Astra.⁴²⁷ At that time, Losec, which initially received patent protection in Europe in 1979 for pioneering a new generation of medicines to treat stomach ulcers, had become the world's best-selling prescription medicine.⁴²⁸ Following dawn raids at the company's premises in the UK and

⁴²³ Id. p.100; See also FTC, '*Generic Drug Entry Prior to Patent Expiration, An FTC Study, July 2002*', p.9. Available at <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf>. Visited on June 20, 2007.

⁴²⁴ See Gunther & Breuvert, pp. 676-80.

⁴²⁵ See Gunther & Breuvert, pp. 669-70.

⁴²⁶ AstraZeneca AB and AstraZeneca Plc.

⁴²⁷ The merger of Astra AB with Zeneca to form AstraZeneca plc was completed in 1999. See AstraZeneca's Brief on Alleged Infringement of Article 82 EC, June 2005, p. 3*.

⁴²⁸ Gunther & Breuvert, p. 677.

in Sweden in 2000, the Commission opened formal proceedings by issuing a Statement of Objections outlining its preliminary findings in 2003.⁴²⁹ At AZ's request, an oral hearing was held in February 2004.

After a six-year investigation, the Commission concluded that AZ had infringed Article 82 EC and Article 54 of the EEA Agreement⁴³⁰ by virtue of certain actions in the 1990s, which allegedly afforded protection to its Losec (omeprazole) products from competition from generic versions in a number of Member States.⁴³¹ AZ was found to hold a *dominant position in the market for proton pump inhibitors (PPIs)* and to have *abused this dominant position by (i) making deliberate misrepresentations* before national patent offices and courts to obtain and preserve extended patent protection, through so-called supplementary protection certificates (SPCs) for Losec; and (ii) *misusing the rules and procedures* applied by national medicines agencies when issuing market authorisations for medicines by selectively withdrawing market authorisations for Losec capsules in various Member States.⁴³²

AZ responded by rejecting the Commission's allegations.⁴³³ According to AZ, the Commission case was 'legally and factually flawed' and the actions of Astra 'misconstrued'. Moreover, AZ argued that the Competition's very narrow definition of the concept of dominance meant that almost any company introducing an innovative product would be at risk of being held 'dominant' with the special responsibility not to impair competition. This, it argued, would discourage such companies from competing on the merits, even though they were not on a true analysis dominant. In AZ's opinion, such a constraint would discourage open competition and ultimately innovation and competitiveness.⁴³⁴

More specifically, AZ argued that it had supplied detailed evidence negating the allegation that Astra had occupied a dominant position in the appropriate

⁴²⁹ European Commission Press Release IP/ 03/1136, '*Commission warns AstraZeneca of preliminary findings in Losec antitrust investigation*', July 31, 2003. Available at <http://europa.eu/rapid/pressReleasesAction.do?reference=IP/03/1136&format=HTML&age=d=1&language=EN&guiLanguage=en>. See also AstraZeneca's press release of 31 July 2003, available at <http://www.astrazeneca.com/pressrelease/571.aspx>. Visited on July 5, 2007.

⁴³⁰ Article 54 of the EEA Agreement contains the same prohibition as Article 82 EC with regard to the EEA. Under Article 5 of Council Regulation (EC) No 2894 of 28 November 1994 concerning arrangements for implementing the Agreement on the European Economic Area '*the Community rules giving effect to the principles set out in [Articles 81 and 82 EC] shall apply mutatis mutandis*. (OJ L 305, 30.11.1994, p. 6). The case law of the ECJ and the CFI in relation to interpretation of Article 82 of the Treaty applies equally to Article 54 of the EEA Agreement. See Article 6 of the EEA Agreement, Article 3 (2) of the EEA Surveillance and Court Agreement, as well as Case E-1/94 of 16.12.1994, paras. 32-35.

⁴³¹ See the Decision, p. 2, recital 2.

⁴³² See the Decision, p. 2, recitals 3-5. See also Gunther & Breuvert, p. 677-78; Lawrance & Treacy, p. 7; Alexander Böhlke, '*Monopolies and Market Dominance: Waiting for Modernisation*', G.C.R. 2005, 8(9) Supp (The European Antitrust Review 2006), 50-52, p. 2. See also www.simmons-simmons.com June 2005, p. 1. Visited on June 20, 2007.

⁴³³ See AstraZeneca's '*Brief on Alleged Infringement of Article 82 EC*', June 2005.

Available at <http://www.astrazeneca.com/sites/7/imagebank/typearticleparam511187/astrazeneca-ec-omeprazole-investigation-brief.pdf>. Visited on June 20, 2007.

⁴³⁴ Id. p. 1.

market in the 1990s. According to AZ, the Commission adopted a narrow and unsustainable product market definition that failed to take account of the competitive constraints imposed on Losec⁴³⁵ by H2 antagonists and competing PPI's.⁴³⁶

In relation to the alleged '*SPC abuse*', AZ did not accept as alleged by the Commission, that Astra made any deliberate misrepresentations to patent offices or courts to obtain or preserve extended patent protection. In AZ's view, '[e]ntitlement to SPCs was sufficiently complex that even the highest German court did not consider the interpretation of the law was clear and asked the ECJ for a ruling on interpretation that was eventually handed down in December 2003'. Moreover, '[t]he ECJ made no suggestion of deliberate misrepresentation on the part of Astra, and AZ maintains that a good faith, reasonable approach was taken at all times.' Furthermore, AZ argued that the Commission had confirmed that it was not alleging that Astra had misused its IPRs in any way. Also, AZ put forward, there was no case law establishing that an Article 82 infringement could arise solely from the way in which a company deals with national patent offices.⁴³⁷

As to the '*MUPS abuse*' allegedly committed by selectively withdrawing market authorisations for Losec capsules and replacing them with the MUPS tablet formulation, AZ argued that these were legitimate business decisions by some of Astra's local marketing companies.⁴³⁸ Finally, AZ argued, that the Commission had not taken into account the fact that generic companies, if they so wished, could have relied on published literature to secure their own marketing authorisations, irrespective of the existence (or not) of Astra's product registrations.⁴³⁹

7.2 The Commission Decision

Nevertheless, the Commission found that AZ had, from 1993 to 2000, abused its dominant position on the PPI market⁴⁴⁰ and thus infringed Article 82 EC (as well as Article 54 of the EEA Agreement) by:

⁴³⁵ According to AstraZeneca 'H2 antagonists were the first products used in the treatment of treatment stomach acid disorders and were the established therapy at the later time of the introduction of Losec, the first PPI. The H2 antagonist Zantac, marketed by GSK, was a leader in this class of medicines. Patents for Zantac expired between 1997-2002 in the UK and US. In 1999, Zantac had worldwide sales of \$1.037bn'. Id. p. 3**.

⁴³⁶ Id. p. 2.

⁴³⁷ Id.

⁴³⁸ According to AstraZeneca, the MUPS formulation offered significant benefits over capsules for certain categories of patients and its launch in 48 countries worldwide belied Commission claims about its selective introduction in Europe. Moreover, product withdrawals were undeniably a part of normal business practice by Astra's local marketing companies and were within the bounds of applicable law. Consequently, it was not unlawful to withdraw the registrations for those products.

⁴³⁹ See AstraZeneca's Brief, p. 3.

⁴⁴⁰ The decision emphasises Losec's unique mode of operation and therapeutic superiority. As a breakthrough product protected by IPRs it effectively creates its own market, leading to AZ's dominance in the period of patent/SPC protection. The decision suggests IP owners are less likely to have such a gatekeeper status outside the pharmaceutical sector. See Sophie Lawrance in *Managing Intellectual Property*, at

- (i) the pattern of misleading representations before patent offices in Belgium, Denmark, Germany, the Netherlands, Norway and the United Kingdom and before national courts in Germany and Norway;⁴⁴¹ and
- (ii) their requests for the surrender of the market authorisations for Losec capsules in Denmark, Norway and Sweden combined with their withdrawal from the market of Losec capsules and launch of Losec MUPS tablets in those three countries.

For these infringements essentially consisting in preventing or delaying market entry of generic versions of Losec (omeprazole based products) the Commission fined AZ €60 million.⁴⁴²

7.2.1 The Two Abuses

The Decision considers that both infringements were committed with the intention of unfairly restricting competition from generics and parallel imports.⁴⁴³ The two abuses will be looked at separately below.

7.2.1.1 Misleading Representations

In relation to the first abuse – *AZ's misleading representations as part of its SPC strategy for omeprazole*⁴⁴⁴ – the Commission found that, beginning in 1993, the applicants had engaged in the pattern of deliberate *misrepresentation* to patent agents, patent offices and national courts in order to obtain SPCs to which they knew they were not entitled for their patented product omeprazole, the active substance in Losec.

According to Regulation 1768/92/EEC,⁴⁴⁵ holders of patents protecting medicinal products are able to apply for an extension of up to five years of the term of their patent beyond the patent period of 20 years by filing for a 'Supplementary Protection Certificate'. SPCs are a means to ensure that pharmaceutical companies will benefit from a period of marketing exclusivity, which is sufficient for them to recoup their initial R&D costs and, *in fine*, to protect pharmaceutical research in the EC.⁴⁴⁶

<http://www.managingip.com/includes/magazine/PRINT.asp?SID=648513&ISS=22412&PUBID=34>.

⁴⁴¹ See the Decision, Article 1, p. 1 and Article 1, p. 2, p. 198.

⁴⁴² *Id.* Article 2 of the Decision. Note that when determining the level of the fine to be imposed on AZ (which technically could have been much higher than €60 million), the Commission took into account the novelty of the case under European competition law as mitigating against heavier financial sanction.

⁴⁴³ See Case T-321/05 – *AstraZeneca v Commission*, Action brought on 25 August 2005 Official Journal C 271, 29/10/2005 p. 24. The Commission relies on evidence suggesting that there was a centrally adopted strategy to reduce competition from generic entrants and, in certain cases, parallel trade. It infers that the conduct was not 'normal' competition on the merits from AZ's awareness that its interpretations of the law were questionable. Compare Sophie Lawrance in *Managing Intellectual Property*, at <http://www.managingip.com/includes/magazine/PRINT.asp?SID=648513&ISS=22412&PUBID=34>.

⁴⁴⁴ See pp. 133-167 of the AZ Decision, in particular pp.166-67 and recitals 773-76.

⁴⁴⁵ Regulation concerning the creation of a supplementary protection certificate for medicinal products, [1992] O.J. L182/1.

⁴⁴⁶ See Gunther & Brevart, p. 678; www.simmons-simmons.com June 2005, p. 2.

Pursuant to Article 19 of the Regulation, products such as Losec, which were already on the market when the Regulation came into force were entitled to SPCs only if their *first marketing authorisation* in the EU was granted *after* certain *cut-off dates*. At the time AZ filed its applications the interpretation of ‘first marketing authorisation’ was far from certain. In fact, it was not until the German Bundesgerichtshof (BGH) made an Article 234 EC reference on the point to the ECJ that the expression was clarified.⁴⁴⁷ Nevertheless, the Commission found that AZ concealed the date on which it had received its first authorisation for Losec (as this was given *prior* to the decisive dates in the Regulation), thereby enabling it to obtain extra protection for Losec in various Member States.⁴⁴⁸ AZ’s pattern of misleading representations and concealment was viewed as an ‘overall SPC Strategy’. On this basis, it was concluded that AZ had abused its dominant position within the meaning of Article 82 EC in Belgium, Denmark, Germany, the Netherlands and the UK and within the meaning Article 54 of the EEA Agreement in Norway. The said abuse, which was found to have been carried out during two stages with a view to preventing, or at least delaying, generic market entry, was of a single and continuous nature.⁴⁴⁹

7.2.1.2 Misuse of Regulatory Procedures

As to the second abuse – *the selective capsule deregistration combined with the tablet/capsule switch as part of AZ’s Losec post patent strategy*⁴⁵⁰ – the Commission found that in 1998/1999 the applicants had operated the strategy of *selectively withdrawing* their original Losec capsules, replacing them with tablets (but maintaining the same dose of active ingredient), and subsequently, following applications by generic firms for authorisation in 1998, requesting the deregistration of the marketing authorisations for the capsules in Denmark, Norway and Sweden.⁴⁵¹

⁴⁴⁷ Case C-127/00, *Hässle AB v Ratiopharm GmbH* [2003] E.C.R. I-14781. The first marketing authorisation was held to be the date of grant of the authorisation to place the products on the market as medicinal products in the Member State in which the application was submitted. (‘According to the judgment [...] it is the technical authorisation which is decisive pursuant to Article 19 of the SPC Regulation.’, see the AZ Decision, recital 740, pp. 158-59.) See also www.simmons-simmons.com June 2005, p. 2.

⁴⁴⁸ ‘...this Decision raises no objections against AZ for having incorrectly interpreted the relevant law (*in casu* the SPC Regulation) [...] but concerns AZ’s pattern of misleading representations to patent agents, patent offices and national courts as part of its overall SPC Strategy for omeprazole. Against this background, the proceedings and the outcome in Case C-127/00 *Hässle* [...] are not decisive for this Decision [...] Any lack of clarity in the SPC Regulation and in particular Article 19 thereof cannot therefore justify AZ’s misleading representations and concealment as part of its SPC Strategy.’ See p. 143 and recital 666 of the AZ Decision. See also Lawrance & Treacy, pp. 7-8.

⁴⁴⁹ The misleading representations were initially made by AZ in the form of its instructions to patent agents and applications to patent offices in relation to omeprazole in June 1993 and November-December 1994 in *inter alia* the six countries mentioned above. Later, AZ also persisted in its misleading representations before the patent offices in Belgium, the Netherlands and the UK as well as before national courts in Germany and Norway. See recitals 773-74 of the AZ Decision.

⁴⁵⁰ See pp. 167-87 of the AZ Decision, in particular pp. 186-87 and recitals 860-62.

⁴⁵¹ Note that Lawrance & Treacy (p. 8) argue that if one compares this part of AZ’s conduct with the established abuse of refusing to supply (since the withdrawal of the Losec

Under the relevant legislation at the time of the deregistration there was some doubt as to whether, as a consequence, the generic applications should be granted. In addition, in at least one case, the regulatory authorities withdrew a parallel import licence for the capsules. Generic firms and parallel importers were in litigation with AZ on this matter with the ultimate involvement of the ECJ.⁴⁵² Following the ECJ's judgements in 2003, Council Directive 2001/83/EEC on the Community Code relating to medicinal products for human use was amended by Directive 2004/27/EEC of 31 March 2004. As the law now stands, the first marketing authorisation for a product will form the basis of a global authorisation which will include subsequent authorisations relating to changes in formulation, strength etc. of the medicine.⁴⁵³ Thus, the withdrawal of the authorisation for one version of the product should not affect access to the market for generic manufacturers or parallel importers.⁴⁵⁴

However, irrespective of any uncertainty at the time of the practice, the Commission found that the strategy of selectively changing from Losec capsules to tablets or selectively withdrawing marketing authorisations for the capsules amounted to misuse of regulatory procedures. This meant that AZ had abused its dominant position within the meaning of Article 82 EC in Denmark and Sweden, and within the meaning of Article 54 of the EEA Agreement in Norway, with a view to preventing, or at least delaying, generic market entry and parallel trade. Also this abuse was of a single and continuous nature, which followed in part from the high degree of centralisation and coordination at the top level within AZ that characterises the abusive behaviour. Moreover, the abusive behaviour was held to have formed part of a common strategy of a pan-European nature.⁴⁵⁵

7.2.2 The Exclusionary Strategies

For the purposes of the present thesis – vexatious litigation – focus will be on the first abuse and the exclusionary strategies directed at generic and research competitors.

marketing authorization in effect deprived generic competitors of something they needed to be able to enter the market), the AZ Decision arguably implies that a dominant company is under an obligation not only to continue to supply existing customers (as is clearly established by case law) but to supply all comers. Under existing case law, obligations to supply new customers have been imposed only in very unusual circumstances, such as 'essential facilities' cases, where access to the facility is indispensable for market entry. 'A marketing authorization for an individual product cannot realistically be regarded as indispensable, as its existence does not preclude others from developing competing drugs for the same indication or, indeed, from compiling their own data.'

⁴⁵² See the preliminary ruling in Case C-223/01, *AstraZeneca A/S v Laegemiddelstyrelsen* [2003] E.C.R. I-11809 and Case C-113/01, *Paranova Oy* [2003] E.C.R. I-4243.

⁴⁵³ See Art.6(1) and Art.10(1) of Directive 2001/83 on the Community Code relating to medicinal products for human use, as amended by Directive 2004/27.

⁴⁵⁴ See Gunther & Breuvart, p. 679; www.simmons-simmons.com June 2005, pp. 2-3.

In order to support its decision, the Commission indicated that the finding of the 'de-registration' abuse 'cannot [...] affect incentives to innovate', in so far as marketing authorisations (unlike patents and SPCs) are not intended to reward innovation, but instead merely give the right to sell products on the market. See recital 843, pp. 181-82.

⁴⁵⁵ See the AZ Decision, recitals 860-61, p.186.

7.2.2.1 Directed at Generic Competitors

Regarding the first abuse, the Commission found not only that the SPCs falsely granted had enabled AZ to threaten and sue competitors,⁴⁵⁶ but also that AZ had continued to rely on the misleading representations in national courts when AZ's initial misleading conduct vis-à-vis the patent offices resulted in proceedings (brought by generic manufacturers with a view to invalidating AZ's SPCs).⁴⁵⁷

Citing *ITT Promedia*,⁴⁵⁸ the Commission argued that such *use of public procedures and regulation, including administrative and judicial processes, may, in specific circumstances, constitute an abuse*.⁴⁵⁹

Moreover, in response to AZ's argument based on the special treatment of IPRs, the Commission, again citing *ITT Promedia*, stated that '*both the acquisition of a right and its enforcement may in themselves constitute an abuse*'.⁴⁶⁰

According to the Commission, *the special responsibility* incumbent on dominant undertakings not to impair genuine undistorted competition also covered the possible use of public procedures and regulations, including administrative and judicial processes, with the clear purpose of excluding competitors.⁴⁶¹

Furthermore, in response to AZ's argument that conduct as a defendant could not be abusive, the Commission added: 'Contrary to the claims by AZ, relying on the judgement in *ITT Promedia*⁴⁶², the Commission has not concluded that *the conduct of defence* cannot constitute an abuse. It simply argued that, *by itself*, such conduct *could not be conceived as forming part of a plan to eliminate competition*. In this case, the Commission has demonstrated that the misleading representations before certain national courts are part of the implementation of such a plan.'⁴⁶³

Whilst '*initiating legal proceedings could, in certain circumstances, be abusive* in so far as the aim was to harass the opposing party by imposing costs and delay upon that party, the conduct of a defence could not be equated, as a matter of course, to the institution of legal proceedings.' Considering that a finding of abuse would severely limit the right of access to courts, such a finding could only be established 'in wholly exceptional circumstances'. However, '[i]n this case, the costs and delays associated with legal proceedings were not the result of AZ's defence, but of AZ's initial misleading representations leading to the granting of SPCs'. In other

⁴⁵⁶ See p. 164, recital 760.

⁴⁵⁷ See recitals 629 and 681, (pp. 136 and 146 resp.); in particular p. 155 f., recital 727 f.

⁴⁵⁸ Case T-111/96 *ITT Promedia*.

⁴⁵⁹ See recital 327, fn. 447, p. 80 and recital 743, fn. 602, p. 159.

⁴⁶⁰ See recital 742 and fn. 601, p. 159, referring to *ITT Promedia*, paragraph 139. See also recital 328, fn. 448, p. 80. Note the way in which the Commission sidelines the distinction between the 'existence' and 'exercise' of IPRs, focussing instead on the concept of the 'subject matter' of the right. See Sophie Lawrance in *Managing Intellectual Property*, at <http://www.managingip.com/includes/magazine/PRINT.asp?SID=648513&ISS=22412&PUBID=34>.

⁴⁶¹ See recital 747, pp. 160-61 (referring to recitals 324-28). See in particular recitals 325, 327 and fn. 446, pp. 79-80.

⁴⁶² *ITT Promedia*, paragraph 42.

⁴⁶³ See recitals 736-37, p. 158.

words, ‘AZ’s conduct of its defence before the national courts concerned was simply the continuation of the pattern of misleading representations initiated by AZ well before the competitors instituted proceedings, and not the cause of the costs and delays suffered by them.’⁴⁶⁴

‘In such circumstances it [was] not necessary to consider whether, by itself, the conduct of a defence based on misleading representations could qualify as abusive on its own, considering that AZ knew perfectly well at the time of making the misleading representations in question that Losec [had not been entitled to extended protection], and could therefore not be said to have asserted, at that moment, rights which it could reasonably have considered to be its own’.⁴⁶⁵

7.2.2.2 Directed at Research Competitors

In addition to these exclusionary strategies directed at generic competitors, the Commission also established that AZ had been able to use both its substance and other patents to exert considerable pressure on its research based competitors Takeda, Byk Gulden and Esai through *patent litigation* in numerous countries. These actions all resulted in overall settlements more or less dictated by AZ. That way, AZ had in effect been able – through its patents – to put pressure on, and raise the costs of, its much smaller competitors.⁴⁶⁶

However, rather than suggesting that AZ’s legal actions had not been legitimate, the Commission viewed the actions instituted by AZ as *relevant when assessing its dominance*.⁴⁶⁷

Through the infringement proceedings, AZ had been able, to a large extent, to dictate the terms of Takeda’s continued existence on certain markets and its right to enter other markets on a worldwide scale.⁴⁶⁸

Moreover, as emerged from internal documents,⁴⁶⁹ a ‘*worldwide campaign of patent litigation* against Byk Gulden had been carefully planned by AZ at the highest level of the company’. The same documents indicated that patent litigation was ‘lengthy and, therefore, costly’, imposing a greater proportionate burden on the smaller competitor.⁴⁷⁰ The fact that Byk Gulden had brought claims for patent invalidity was in the Commission’s view irrelevant, as the bringing of counterclaims was held to be a standard defensive reaction of a company subjected to patent infringement proceedings in the pharmaceutical sector. It did not put the company sued on an equal footing vis-à-vis the litigant.⁴⁷¹

⁴⁶⁴ See recital 738, p. 158.

⁴⁶⁵ See recital 739, p. 159, referring to *ITT Promedia*, paragraphs 73, 93, 111 and 116.

⁴⁶⁶ See recitals 87-96, pp. 21-23 and recitals 521-5, p. 117.

⁴⁶⁷ See recital 535, p. 120.

⁴⁶⁸ See recital 537, p. 120.

⁴⁶⁹ (See recital 93.)

⁴⁷⁰ (See recitals 78-86.)

⁴⁷¹ See recitals 538-39, p. 120.

7.2.3 The ‘Vexatious Litigation Doctrine’ Post *AstraZeneca*

AstraZeneca is the first antitrust case in which the Commission has tackled misconduct before national authorities in the pharmaceutical industry on the basis of Article 82 EC. The Decision, which represents a step further in the Commission's already strict approach to sanctioning restrictions on parallel imports and on market access for generic products,⁴⁷² introduces abuse of the patent system as a novel type of infringement of Article 82 EC and lays down that delaying generic entry is an abuse of a dominant position.⁴⁷³

Arguably, however, the *AstraZeneca* decision also reaffirms and clarifies the earlier ‘vexatious litigation doctrine’ developed in *ITT Promedia*. Alone the fact that the Commission in its Decision refers seven times to that case,⁴⁷⁴ may be seen to support such a conclusion. In relation to the *conduct of defence* as a potential abuse under Article 82 EC, it could even be argued that the Commission has taken the *Promedia doctrine* one step further.⁴⁷⁵

On the other hand, the Commission does not once comment or develop on the *ITT Promedia* criteria. Nor does it view AZ’s litigation tactics on its own as an abuse. Instead, it uses the litigation tactics to support its finding of dominance as well as the overall picture of AZ’s abusive strategy originating in the misleading representations.⁴⁷⁶ From these considerations one could draw the conclusion that the Commission in its *AstraZeneca* decision clearly was not able or willing to fully give effect to an EC ‘vexatious litigation doctrine’.

Irrespective of which opinion one favours, the Decision leaves many questions unanswered, hopefully to be clarified in the pending appeal.⁴⁷⁷

7.2.3.1 Can Groundless Threats Suffice?

First, while it appears more or less settled that the vexatious *institution of legal proceedings* could constitute an abuse, the *AstraZeneca* decision did not give much guidance as to *groundless threats* and the question whether this could amount to an abuse under Article 82 EC.⁴⁷⁸

7.2.3.2 Conduct of Defence as an Abuse?

Second, whilst the Commission clarifies that the *conduct of defence* could not be equated, as a matter of course, to the *vexatious institution of legal proceedings*, and though by itself, such conduct could not be conceived as forming part of a plan to eliminate competition, the Commission

⁴⁷² See Gunther & Breuvart, p. 679. See also Lawrance & Treacy, p. 8, where it is argued that ‘comparisons with existing types of abuse [under Article 82 EC] suggest that the Commission is pushing the boundaries of the provision’.

⁴⁷³ See Gunther & Breuvart, p. 669; Lawrance & Treacy, p. 7.

⁴⁷⁴ See the Decision, fn. 446-48 (p. 80); p. 158 and fn. 597-98; fn. 601-2 (p. 159).

⁴⁷⁵ See below.

⁴⁷⁶ Compare above.

⁴⁷⁷ Case T-321/05, *AstraZeneca v. Commission*, Action brought on 25 August 2005.

⁴⁷⁸ In this respect, the stance taken in *ITT Promedia* was thus maintained.

nevertheless states that *the conduct of a defence cannot be ruled out as an abuse*. However, as the Commission did not find it necessary, on the facts of the case, to consider whether, by itself, the conduct of defence based on misleading representations could qualify as abusive on its own, this important question was left unanswered.⁴⁷⁹

7.2.3.3 Harassing Litigation as a Factor Indicating Dominance?

Third, in relation to the *legal actions* against the research competitors, the Commission does not question AZ's assertion that these were legitimate, but states that 'the legal actions instituted by AZ are nevertheless highly relevant for assessing its dominance in this case'. Considering that it had been proven that AZ saw these patent litigations as a practical and effective measure to impose a burden on smaller competitors, this approach may seem somewhat odd. Was this kind of behaviour not exactly of the harassing kind that should itself constitute an abuse under *ITT Promedia*?

7.2.3.4 Widening of the Special Responsibility?

Finally, it seems that the rather vague concept of *special responsibility* incumbent on dominant undertakings now covers the even vaguer 'doctrine of vexatious litigation' in cases where legal proceedings are used with an exclusionary intent.⁴⁸⁰ Consequently, the many uncertainties surrounding the potential abuse are likely to impose a heavy burden on dominant undertakings, or undertakings that fear that they might be considered to be dominant. This is especially so in industries such as the pharmaceutical industry, in which IPRs are of particular significance and where infringement actions, and the threat of such actions, are commonplace.⁴⁸¹

7.3 The Pending Appeal

In the appeal brought on 25 August 2005, AZ is seeking to quash the Commission's Decision. The applicants challenge it on several levels;

(i) First of all, AZ alleges that the Commission mistakenly defined *the relevant market* as being only that of proton pump inhibitors (PPIs), used for the treatment of gastrointestinal acid related diseases, and excluded histamine receptor antagonists (H2 blockers) from the relevant market.

⁴⁷⁹ Still, if contrasted with the less permissive statements in *ITT Promedia*, the reasoning in the *AstraZeneca* decision may nevertheless be seen as a development.

⁴⁸⁰ See recital 747, p. 160: 'In any event, the special responsibility incumbent on dominant undertakings not to impair genuine undistorted competition on the common market also covers the possible use of public procedures or regulations with the clear purpose of excluding competitors, in particular where the authorities or bodies applying such procedures or regulations have no or little discretion (see recitals (324)-(328)).'

⁴⁸¹ Whish, p. 680. See also Lara J. Glasgow, '*Stretching the Limits of IPRs: Has the Pharmaceutical Industry Gone Too Far?*', 41 IDEA 227 (2001), at 231. Available at http://www.idea.piercelaw.edu/articles/41/41_2/2.Glasgow.pdf. Visited on June 20, 2007. See further Gunther & Breuvert, p. 669.

(ii) According to AZ, the contested Decision does not consider whether the applicants would still be in a dominant position if H2 blockers were included in the relevant market. Obviously, such a market definition would influence the Commission's finding of *dominance*.

The applicants further challenge the Commission's findings of infringements on legal grounds;

(iii) Regarding the alleged *misrepresentations* with respect to patents, AZ considers that such misleading representations made in the course of applications for IPRs cannot in law amount to an abuse unless and until the dishonestly obtained rights are enforced or are capable of being enforced.

(iv) AZ also consider that Article 82 EC, properly interpreted, did not impose on them an obligation to maintain a *marketing authorisation* for a product they no longer marketed, merely because it would make it easier for generics and parallel traders to compete with it.

The applicants also challenge the Commission's findings of infringement on factual ground.

(v) AZ submits that the Commission failed to adduce *evidence proving to the correct legal standard [in relation to] the alleged abuse of IPRs* and that, furthermore,

(vi) there was *no strategy for selectively changing* from 'Losec' capsules to tablets or *selectively withdrawing* marketing authorisations for the capsules.⁴⁸²

Like other cases on anti-competitive abuses, the *AstraZeneca* decision is clearly controversial. The final word as to whether it was merely competing on the merits or whether it is guilty of abusive behaviour has not yet been spoken. Indeed, there is a very fine – sometimes invisible – line between these two positions,⁴⁸³ especially, where as here, the facts are subject to dispute and new abuses are involved. There is no doubt that the pending appeal is about to set a very important example. It will be interesting to see whether the CFI follows the Commission's line of reasoning. However, it is not unlikely that the ECJ will have the final word.⁴⁸⁴

Until then, pharmaceutical companies holding a dominant position in the Community will need to take care that their conduct towards national authorities does not lead to foreclosure of competition by blocking or delaying market access for generic versions or parallel imports of their protected medicine.⁴⁸⁵ This effect of the decision may, as will be seen in the next section, be easier to reconcile with the body of US cases where certain abuses of administrative systems as well as of the court process have been held to infringe antitrust law, than with the Article 82 review process which aims at adopting a more flexible, economics-based approach and at encouraging innovation.

⁴⁸² See the pending appeal, Case T-321/05, *AstraZeneca v. Commission*, OJ 2005 C271/24.

⁴⁸³ Compare Whish, p. 196-97.

⁴⁸⁴ Compare www.simmons-simmons.com, p. 1.

⁴⁸⁵ *Id.* pp. 1 and 3.

8 Vexatious Patent Litigation – EC & US Approaches Compared

As shown above, case law regarding anticompetitive patent infringement actions on the interface between IP and competition law keeps evolving, until now mainly on a US – but gradually it seems, also on an EC – basis.⁴⁸⁶

However, while vexatious litigation issues have given rise to several landmark cases in the US, the Community Courts have so far neither explicitly challenged this kind of anticompetitive behaviour, nor fully recognised any vexatious litigation doctrine under Article 82 EC.

Part of the explanation for this may be that the behaviour in question hitherto has been rare in the EC. In addition, in the EC (unlike in the US) a vexatious litigant could only ever be caught if implemented by a company which is dominant in the first place, something which further reduces the number of cases which could form a basis for a developing doctrine.

Nevertheless, with the recent *AstraZeneca decision* provided by the European Commission, there is now clear case law on both sides of the Atlantic to challenge abuses of governmental procedures – including the court process – in relation to IPRs. In particular, this is the case where the misuse of IPR systems and procedures is aimed at extending IP protection (so-called ever-greening) and, thereby, at blocking or delaying potential competitors from entering the market.⁴⁸⁷ Arguably, this may have opened the door for further convergence in the vexatious litigation context.

8.1 Curtailment of the Right to Bring Patent Infringement Actions

The fact that patent litigation, when pursued as a strategy, generally involves extremely high stakes tends to increase its strategic and competitive importance to firms interested in excluding unwanted rivals. Instituting patent infringement proceedings clearly represents one potential way in which undertakings exploit the right of access to the courts for competitive and strategic benefit. That way, private litigation against competitors creates a potential tool for harassing, harming and extorting them.⁴⁸⁸ To prevent such use of the court process, the US and EC systems

⁴⁸⁶ Eccles & Ferla, p. 8.

⁴⁸⁷ See Lawrence & Treacy, p. 7; Eccles & Ferla, p. 8.

⁴⁸⁸ Compare R. Preston McAfee1 and Nicholas V. Vakkur, *The Strategic Abuse of the Antitrust Laws*, Journal of Strategic Management Education 2004 1(3), Senate Hall Academic Publishing, pp. 3-4. As it is likely to be much more expensive for the defendant firm to defend against a patent infringement lawsuit than for the plaintiff firm to bring the suit, vexatious litigation is a useful strategic tool in attacking a rival. One way for the defendant to defend themselves is to attack in response. Antitrust suits are frequently filed

(as was seen above) have invented different rules that, albeit subject to strict conditions and only in exceptional circumstances, can restrict the fundamental right of access to the courts. The question is however, if the rules really are as different as they at first glance may seem. Perhaps it may even be argued that the Commission's *AstraZeneca* Decision constitutes proof of an EC approach converging with the different approaches in the US. It may thus be worth comparing the Commission's approach in *AstraZeneca* with the three main US theories examined above, each of which warrant exception from the *Noerr-Pennington immunity* and thereby the right of access to the courts.

8.2 EC and US Convergence?

As was seen above, a vexatious plaintiff's purposeful anticompetitive conduct will be caught under Section 2 of the Sherman Act if the plaintiff company *obtains a patent by committing a Walker Process fraud on the PTO and then attempts to enforce that patent on its competitor*. According to the Commission allegations, AZ had obtained not its patent, but the SPCs as a direct result of its misrepresentations before the national patent offices, and then tried to enforce the extended patent protection on its competitors in the national courts, not only through the conduct of defence (in relation to its generic competitors), but also through infringement actions initiated by AZ itself (against its research competitors). Even if one would accept AZ's argument concerning the legal uncertainty and that the SPCs were not secured by fraud, the fact would still remain that AZ eventually did come to know that the certificates were invalid, but still pursued the infringement actions. In the US, AZ's behaviour would therefore most likely be viewed as problematic under the *Walker Process doctrine*. However, upon a comparison with the reasoning in the actual Decision it is evident that the Commission did not seek to take the *Promedia doctrine* this far. Indeed, an independent abuse in 'Walker Process form' therefore seems unlikely to receive recognition in the Community, at least within the nearest future.

However, as was also seen above, a litigant enforcing its IPR may also lose antitrust immunity and violate Section 2 of the Sherman Act if the lawsuit is held to be a '*sham*' under the two-fold *Professional Real Estate (PRE) test*. As was pointed out above, the Commission's *AstraZeneca* decision states that 'AZ knew perfectly well at the time of making the misleading representations in question that Losec [had not been entitled to extended protection], and could therefore not be said to have asserted, at that moment, rights which it could reasonably have considered to be its own'. Nor can AZ or any reasonable litigant therefore realistically have expected success on the merits, as AZ both knew that the SPCs were invalid *and* that there therefore had been no infringement of the patent right. As to AZ's subjective motivation, it is evident from the internal documents that the baseless lawsuits concealed an attempt to interfere directly with the business

in response to other suits, because they balance the settlement process and make the imposition of costs more symmetric.

relationships of a competitor, through the use of the court process as an anticompetitive weapon. Consequently, it seems likely that AZ's behaviour, in the US, would not escape the reach of the *sham litigation doctrine* either. Again, however, the Commission found it more convenient to chose another, less controversial route to support its finding of abuse.

It then remains to be examined whether the Commission's reasoning shares any common features with the last of the US theories presented above. Under this doctrine, a patentee may incur antitrust liability when bringing a patent infringement lawsuit, *even absent bad faith, where the infringement suit is part of a larger monopolization scheme that would violate Section 2 of the Sherman Act*. Considering the facts of the *AstraZeneca* case as presented above, it seems that a US court would have strong reasons for a finding of abuse on this ground. Moreover, upon a comparison with the reasoning in the actual decision, it seems apparent that the Commission's approach strongly resembles this *monopolization scheme doctrine*. In particular, the Commission neither suggests that AZ's legal actions against its research competitors were instituted in bad faith, nor does it view AZ's lawsuits on their own as an abuse. Rather, it uses the infringement proceedings to support its finding of dominance and as part of AZ's scheme to monopolise.

On this basis, it seems at least conceivable that, despite the specificities of the US and EC patent and antitrust systems, the conduct deemed to be unlawful under Article 82 EC as blocking or delaying generic market entry would also have been prohibited if considered under Section 2 of the Sherman Act, and *vice versa*.

Hence, although one may argue that the notions of monopolization under Section 2 of the Sherman Act and abuse of a dominant position under Article 82 EC are not identical, they seem to lead to analogous solutions when applied to the strategies employed by brand name pharmaceutical undertakings to block or delay generic market entry.

Moreover, as may be seen from an examination of the case law, the decisions emanating from the US and EC competition authorities seem to have an influence on each other.⁴⁸⁹ Particularly, the European Commission seems to have been influenced by US precedents in its *AstraZeneca*

⁴⁸⁹ In the US, the *AstraZeneca* case and, more specifically, the finding of the 'de-registration abuse', although unlikely to be replicated in the EC, might have an influence on a number of private antitrust actions pending before US district courts, in which the plaintiffs are alleging a novel theory of antitrust liability – as opposed to the classic theories based on patent obtained by *fraud* or *sham* litigation – based on so-called '*anti-competitive life cycle management*' of drug products by the brand name drug companies concerned. Basically, these lawsuits allege that the brand name drug companies engaged in exclusionary anticompetitive schemes by reformulating their products and 'managing their life cycle'. Since these allegations seem to some extent similar to AZ's replacement of its Losec capsules with a tablet formulation, combined with requests to European national medicines agencies to deregister the market authorisations for the capsules, it is likely that the Commission's finding of a 'de-registration abuse' will have an influence on how these cases are dealt with by the US district courts. See Gunther & Breuvert, pp. 681-82.

decision.⁴⁹⁰ In the future, it will be interesting to see whether the Commission keeps following in the footsteps of the US Courts and the FTC by penalising the obtaining and/or enforcement of patents against generic manufacturers through objectively baseless patent litigation.

8.3 Private Antitrust Enforcement & Patent Litigation Insurance

(i) Private Antitrust Enforcement – From the perspective of a drug manufacturer subject to proceedings in the US or the EC, any similarities between the respective approaches of the FTC and the Commission, while important, are likely to be overshadowed by one of the key differences currently existing between the two jurisdictions – the issue of the financial consequences of their actions.

In the US, while the FTC's focus is often on imposing behavioural remedies on the company to prevent repetition of the prohibited conduct, a significant financial threat exists in the form of private antitrust actions, including not only antitrust actions initiated by generic competitors (claiming damages for the profits they lost as a result of the antitrust violation), but also private class actions initiated by drug purchasers.⁴⁹¹ If these latter plaintiffs are successful in proving antitrust liability, they are entitled to damages amounting to the difference between the price effectively paid and that which they would have paid but for the brand name company's alleged antitrust violation (i.e. if the generic manufacturers had not been restrained from entering the market). Depending on the size of the market for the medicine, and the length of the period over which the unlawful conduct was deemed to range, this of itself could amount to a significant financial penalty. Of even greater concern for the defendant company, however, is that the total damages award would be trebled pursuant to Section 4 of the Clayton Act.⁴⁹² Much due to this, the US continues to be the centre of gravity for private antitrust litigation in terms of the volume of litigation.

⁴⁹⁰ The Commission has explicitly acknowledged the influence of US case law in its reasoning by indicating that 'misrepresentations before patent offices and misuse of regulatory procedures for the authorisation of medicines have previously been held to be antitrust violations by US courts and the FTC.' See Press Release IP/03/1136, July 31, 2003, *Commission warns AstraZeneca of preliminary findings in Losec antitrust investigation*, available at <http://europa.eu/rapid/pressReleasesAction.do?reference=IP/03/1136&format=HTML&age=d=1&language=EN&guiLanguage=en>.

⁴⁹¹ Such class actions are invariably brought in parallel to any ongoing FTC proceedings, but may also be initiated even where the FTC decides not to investigate a manufacturer's practices itself. Furthermore, direct and indirect purchasers of a pharmaceutical product constitute separate classes, and each has standing to bring a damages claim for loss suffered as a result of the allegedly unlawful practices.

⁴⁹² S. 4 (a) of the Clayton Act states that 'any person who shall be injured in his business or property by reason of anything forbidden in the antitrust laws may sue therefor in any district court of the United States in the district in which the defendant resides or is found or has an agent, without respect to the amount in controversy, and shall recover threefold the damages by him sustained, and the cost of the suit, including a reasonable attorney's fee'. The spectre of such potentially huge damages awards has undoubtedly influenced the decision of the defendants in such cases to enter into settlement agreements with the

Due to a number of practical and legal obstacles to the commencement of proceedings, such *wide scale private enforcement* has not been replicated in the EC. Since the case of *Courage v Crehan*,⁴⁹³ it has been clear that some form of remedy should be available to those harmed by infringements of Articles 81 or 82 EC.⁴⁹⁴ However, any action must be brought at a national level, and must comply with the various legal and procedural requirements of the relevant Member State.

To facilitate private enforcement and follow up on the decentralisation of the EC competition laws triggered by the passing of Regulation No. 1/2003 in 2004, the Commission sponsored a comprehensive review of the conditions under which private parties can bring actions for damages before national courts for breaches of EC competition laws.⁴⁹⁵

As was noted by the subsequent *Comparative Report*, the state of private enforcement in the EC is in a state of 'total underdevelopment', with an 'astonishing diversity' existing between the systems adopted by various Member States. Various barriers to action faced by private plaintiffs were identified,⁴⁹⁶ which, while varying in intensity from country to country, collectively serve to reduce the number of private actions brought.⁴⁹⁷ In spite of various efforts made at dealing with these issues,⁴⁹⁸ Competition Commissioner Mario Monti, prior to leaving office, acknowledged that 'much more needs to be done.'⁴⁹⁹

plaintiffs (without acknowledging any wrongdoing). Such settlements have themselves imposed substantial payment obligations on the brand name manufacturers. For example, the total settlements agreed upon in relation to *BuSpar*, *Taxol* and *Platinol* amounted to \$535 million, \$135 million and \$50 million respectively.

⁴⁹³ Case C-453/99, *Courage v Crehan* [2001] E.C.R. I-06297.

⁴⁹⁴ See also *Crehan v Inntrepreneur* [2004] EWCA 627 (judgement by an English court awarding damages in a competition case); *Provimi Ltd v. Roche Products Ltd et al*, [2003] QBD (6 May 2003) (holding that a non-English claimant suffering injury outside of England may sue non-English cartel participants in English courts so long as the cartel included English participants).

⁴⁹⁵ Ashurst, 'Study on the conditions of claims for damages in case of infringement of EC competition rules – Comparative Report', August 31, 2004, available at http://europa.eu.int/comm/competition/antitrust/others/private_enforcement/index_en.html.

⁴⁹⁶ These include: confusion as to the legal basis for bringing a claim; the lack of specialised competition courts to hear claims; difficulties in consumers obtaining standing to pursue claims; restrictions on the ability to bring class actions; heavy evidential burdens on the plaintiff (both regarding proof of anticompetitive conduct and a causal nexus between such conduct and the loss suffered, particularly in jurisdictions with limited disclosure obligations); the absence of punitive damages and procedural difficulties, be they short limitation periods or unduly long proceedings. It is important to note that these obstacles to private enforcement are not necessarily perceived as 'problems' that require solutions. To the contrary, the working paper expressly warns against an unqualified move towards the system in the United States, see below. For further analysis, see Tony Woodgate and Jane Jellis, 'Private EC Antitrust Enforcement', available at www.globalcompetitionreview.com/ear/private.cfm. Visited on June 20, 2007.

⁴⁹⁷ According to the report, as at October 2004, there had only been 12 successful damages awards for breach of competition law since the EC antitrust enforcement system was set up in 1962.

⁴⁹⁸ Efforts made by the Commission, include e.g. programs to improve the training of judges in EC competition law and the creation of a database of EC competition law based actions brought in the Member States.

⁴⁹⁹ Mario Monti, 'Private litigation as a key complement to public enforcement of competition rules and the first conclusions on the implementation of the new Merger

Against this background, the Commission in late 2005, continued its efforts to enhance enforcement by issuing a *Green Paper*,⁵⁰⁰ accompanied by a detailed *Commission Staff Working Paper*.⁵⁰¹ The Green Paper focused on a number of the procedural hurdles identified in the Comparative Report, and invited public comments to specific questions presented.⁵⁰²

Far from seeking radical changes, the Green Paper aims for cautious reform and an optimal balance between the benefits and costs of private litigation. Even if private enforcement is regarded as an important complement to public enforcement that should be facilitated, the Commission seems very conscious of the risks of falling into the excesses seen in the USA: 'The US system is often perceived as encouraging *unmeritorious* or *vexatious litigation*. This system should be examined carefully and lessons drawn from it, as well as from the experiences of other foreign jurisdictions in this field, as appropriate. The protection of rights deriving from community competition law is important, but it is also important to keep excessive litigation in check and to try to achieve some form of moderation in the enforcement system.'⁵⁰³

Hence, although the Commission has pushed for critical developments for a more active private enforcement scheme, it would be unrealistic to expect that this will lead to a system that closely resembles the US model.⁵⁰⁴

In any event, the success and effects of any reforms will not be calculable for some time, and in the meantime, the ability of the threat of private actions to act as a deterrent against pharmaceutical companies' abusive practices will remain substantially less significant in the EU than in the USA.⁵⁰⁵ Nevertheless, there is no doubt that enforcement agencies are no longer the sole enforcer of competition laws – private enforcement of competition laws will expand its role outside the US in ensuring competitive markets and consumer welfare.⁵⁰⁶

(ii) Patent Litigation Insurance – Closely linked to the issue of private enforcement is the current plans to introduce a *Patent Litigation Insurance (PLI) Scheme* in Europe. Following the first study commissioned by the DG

Regulation', Speech to the 8th Annual Competition Conference of the IBA, Fiesole, September 17, 2004.

⁵⁰⁰ The '*Green Paper – Damages actions for breach of the EC antitrust rules*', 19.12.2005, COM(2005) 672 final, is available at http://eur-lex.europa.eu/LexUriServ/site/en/com/2005/com2005_0672en01.pdf. Visited on June 20, 2007.

⁵⁰¹ The '*Staff Working Paper*', SEC(2005) 1732 (Annex to the Green Paper), is available at http://ec.europa.eu/comm/competition/antitrust/actionsdamages/sp_en.pdf. Visited on June 20, 2007.

⁵⁰² Green paper at 12.

⁵⁰³ Green paper para 47 (emphasis added).

⁵⁰⁴ Charles E. Koob, David E Van Jr and Arman Y Oruc, '*Developments in Private Enforcement of Competition Laws, Getting the Deal Trough*' – Private Antitrust Litigation 2007, pp. 3-7.

⁵⁰⁵ Gunther & Breuvart, pp. 682-83.

⁵⁰⁶ Charles E. Koob, David E Van Jr and Arman Y Oruc, pp. 3-7. See also Eddy De Smijter, Constanze Stropp and Donncadh Woods, *Directorate-General Competition, unit A-1, 'Green Paper on damages actions for breach of the EC antitrust rules'*, EC Competition Policy Newsletter, No. 1 – Spring 2006, pp. 1-3, available at <http://europa.eu.int/comm/competition/publications/cpn>.

for Internal Market and Services in 2002,⁵⁰⁷ and in the light of the need for definitive conclusions, a follow-up study was commissioned in 2004 with the aim to evaluate on a highly detailed basis, the feasibility of a small number of insurance schemes for insuring European Patents (and, when they exist, Community Patents) against patent litigation risks.⁵⁰⁸ The Report considered that ‘patent litigation insurance has long been considered potentially important as a means of ensuring access to patents to small and medium-sized enterprises [SMEs] which do not have extensive legal resources and are put off from developing, patenting or litigating patents on new technologies owing to the expense and complexities in EU patent systems.’⁵⁰⁹

In short, the Report found that it had been demonstrated that industry on the whole would welcome a widespread PLI scheme and that this would particularly benefit SMEs. Since a mandatory scheme would be viable, premiums could be affordable and some insurers willing to enter at the outset it was concluded that a scheme could succeed.⁵¹⁰ A PLI scheme would arguably avoid the unsatisfactory status quo, have beneficial effects on the patent system and facilitate the desired technical advance in the EU.⁵¹¹

Very little space in the Report was given to the issue of vexatious or frivolous litigants. In essence, all that was said was that, ‘[t]he problem of *vexatious litigants* is answered by the application of excess and co-insurance. In addition, of course, no action which qualified for insurance support because it had a 51% or better chance of success could be called vexatious or frivolous.’⁵¹² Although settlement would be encouraged, ‘the right to fight would always be preserved (subject to the risk assessment) in order to retain the validity of the patent system.’⁵¹³

8.4 Anticipating Future Approaches

Apart from the *European Commission’s Communication* entitled, ‘*A stronger EU-US Partnership and a more Open Market for the 21st century*’,⁵¹⁴ in which the Commission acknowledges that the EC and US

⁵⁰⁷ The 2003 Report can be consulted on

http://europa.eu.int/comm/internal_market/en/indprop/patent/index.htm.

⁵⁰⁸ See ‘*The feasibility of possible insurance schemes against patent litigation risks – a study for the European Commission by CJA Consultants Ltd*’ – February 2006. Available at http://ec.europa.eu/internal_market/indprop/patent/index_en.htm.

⁵⁰⁹ See the Report, p. 11.

⁵¹⁰ See the Report, p. 16.

⁵¹¹ See the Report, p. 14.

⁵¹² See section 14.21.1 of the Report, p. 44 (emphasis added). See also p. 15 where it is stated that ‘the patentee would be liable for the cost, save when defence was involved, unless the assessment of its chances was 51% or better’.

⁵¹³ See the Report, p. 15.

⁵¹⁴ Communication from the European Commission to the Council, the European Parliament and the European Economic and Social Committee: *A stronger EU-US Partnership and a more open market for the 21st century* 18.5.2005, COM(2005) 196 final, available at http://ec.europa.eu/external_relations/us/revamping/com2005_196_en.pdf. Visited on June 20, 2007. The Commission Communication contains a wide range of practical policy proposals for a joint EU-US strategy to boost economic integration.

economies have become ever more intertwined and therefore calls for better and reinforced regulatory antitrust policy co-operation, such transatlantic harmonisation initiatives have so far been limited to certain areas of antitrust policy such as merger control and international cartels.⁵¹⁵

The interface between antitrust and IP law is probably one of the areas where important differences remain between the US and the EC. Given the increasingly global nature of the corporations and products involved, this may seem surprising. Nevertheless, the influence that the decisions of US and EC competition authorities have on each other must not be underestimated. Arguably, the Commission's *AstraZeneca* decision and its implications on the IP and competition law interface signify that the transatlantic influence even goes beyond the previous cooperation and harmonisation efforts. Hence, the Decision constitutes proof of subtly developing transatlantic co-operation and harmonisation of antitrust policies, including the IP and antitrust interface.⁵¹⁶

Consequently, the current pro-IP approach applied in the US, is likely to influence coming trends in the EC too. Past and recent evolutions in US case law, as well as speeches by representatives of the US Agencies, indicate that intervention in the antitrust and IP interface will be limited to blatant cases of monopolization that directly harm consumers, such as misrepresentations to the PTO to delay market entry or vexatious patent litigation. Another closely related area where the US agencies seem ready to intervene is that of *settlements* of patent disputes in the pharmaceutical industry. Recently, such settlements arising between branded pharmaceutical undertakings and generic competitors have been under considerable scrutiny by the US competition agencies. In particular, there has been significant FTC interest in settlements that are alleged to involve a patent owner paying an alleged infringer in return for an agreement by the infringer not to compete in the relevant market.⁵¹⁷ This general trend was reinforced by the *Medicare Prescription Drug, Improvement and Modernization Act 2003*, which requires brand-name companies and generic producers to file their brand-generic settlement agreements with the FTC and DoJ.⁵¹⁸ Although '[most] patent settlements probably are pro-

⁵¹⁵ E.g., the European Commission and the Agencies are working together to promote convergence among the world's antitrust enforcers, notably within the International Competition Network (ICN). However, until now, the ICN has mostly concentrated its efforts on merger control, issuing recommendations to improve competition agencies' merger review processes. The IP and antitrust interface has not yet been on the agenda.

⁵¹⁶ Compare Eccles & Ferla, pp.8-11.

⁵¹⁷ See Chairman Timothy J. Muris, 'Prepared Statement of The Federal Trade Commission Before the Committee on Commerce, Science, and Transportation', United States Senate (Washington, D.C., Apr. 23, 2002) available at <http://www.ftc.gov/os/2002/04/pharmtestimony.htm>. Visited on June 20, 2007. The FTC has also more recently stressed that exclusion payments in pharmaceutical patent settlements harm competition. See 'Anticompetitive Settlements in the Pharmaceutical Industry, Prepared Statement of the Federal Trade Commission Before the Committee on the Judiciary of the United States Senate' (January 17, 2007), available at http://www.ftc.gov/speeches/leibowitz/070117anticompetitivepatentsettlements_senate.pdf. Visited on June 20, 2007.

⁵¹⁸ Balto & Wolman p. 82; See also Eccles & Ferla, p. 3.

competitive or competitively neutral'⁵¹⁹ and constitute efficient means to avoid costly and time-consuming litigation,⁵²⁰ the US agencies see a number of potential antitrust concerns that may arise in the settlement context.⁵²¹ First, there is a public interest in the determination of whether the patent really is valid or properly procured. As was noted in *Glaxo Group Ltd.*,⁵²² '[i]t is as important to the public that competition should not be repressed by worthless patents, as that the patentee of a really valuable invention should be protected in his monopoly.'⁵²³ Secondly, the terms of the settlement may actually delay or prevent the entry of a competing product, or divide a market between competitors.⁵²⁴ Furthermore, the settling challenger may have important evidence about the validity of the patent that may be lost in the settlement.⁵²⁵ Thus, a patent settlement may serve the interests of the parties at the expense of consumers and competitors.⁵²⁶ Although, this particular problem has so far not received the same kind of attention in the EC, it is likely that it will in the near future.⁵²⁷

More generally, however, the issue of the exercise of IPRs as an abuse of a dominant position is being examined in the still ongoing *Article 82 EC Review* conducted by the European Commission.⁵²⁸ This reform has been, and is, an important opportunity for the Commission to clarify and adjust its approach to abusive use of IPRs. Read in the light of the *EAGCP Report*,⁵²⁹ there seems already to be a developing trend in Europe to stress the importance of IPRs and, sometimes, its supremacy over competition law. As a result, when analysing cases involving e.g. allegedly abusive misuse of patent and drug regulatory approval systems, the Commission will have to take into account not only the exclusionary effects of the conduct vis-à-vis generic drug competitors, but also the potential pro-competitive effects and efficiencies of the conduct, as well as the effects that its own enforcement actions might have on returns on investments and incentive to innovate in the research-based pharmaceutical industry.⁵³⁰

⁵¹⁹ See generally David A. Balto, 'Pharmaceutical Patent Settlements: The Antitrust Risks', 55 Food & Drug L.J. 321, 327-28 (2000).

⁵²⁰ Licensing Guidelines, supra n. 89, at § 5.5.

⁵²¹ Commissioner Thomas Leary, 'Prepared Remarks, Antitrust Issues in Settlement of Pharmaceutical Patent Disputes' (Chicago, Ill., Nov. 3, 2000)

<http://www.ftc.gov/speeches/leary/learypharma.htm>. Visited on June 20, 2007.

⁵²² *U.S. v. Glaxo Group Ltd.*, 410 U.S. 52 (1973).

⁵²³ *Id.* at 58 (quoting *Pope Mfg. Co. v. Gormully*, 144 U.S. 224, 234 (1892)).

⁵²⁴ See *Andrx Pharmaceuticals, Inc. v. Biovail Corp. Intl.*, 256 F.3d 799, 811 (D.C. Cir. 2001) (provisions in the settlement 'were not necessarily ancillary restraints but rather could reasonably be viewed as an attempt to allocate market share and preserve monopolistic conditions.')

⁵²⁵ *United States v. Singer Manufacturing Co.* 374 U.S. 174, 195-96 (1963).

⁵²⁶ Balto & Wolman, p. 82.

⁵²⁷ Compare e.g. AZ's conduct in relation to its research competitors in the AZ Decision.

⁵²⁸ See http://ec.europa.eu/comm/competition/antitrust/others/article_82_review.html.

⁵²⁹ The Economic Advisory Group on Competition Policy is an independent group of experts commissioned by the Chief Economist of the Directorate General for Competition (DG Comp). This report was specifically commissioned to provide the Commission with an economic approach to Article 82 and, consequently, to give an opinion on the reform of the Commission's policy on the abuse of dominant position.

⁵³⁰ Gunther & Breuvar, p.

The ‘pro-IP trend’ also seems to be endorsed by the European Competition Commissioner Neelie Kroes, who has clarified that promoting innovation is a top priority on her agenda.⁵³¹ In addition, DG Competition has released a *Consultation document on state aid for innovation*,⁵³² which, amid other things, identifies the ‘problems affecting innovation in Europe’.⁵³³ Amongst those problems, the Commission stresses the ‘unsatisfactory IP protection’ and the ‘unattractive risk/reward ratios for investing in radically innovative products’.⁵³⁴

Yet, the Commission continues to take on a hard stance in relation to the alleged anticompetitive use of IPRs by dominant undertakings, particularly in the pharmaceutical industry. Since the adoption of the *AstraZeneca* decision, Commissioner Kroes explained to the European Parliament in response to an oral question in the Summer of 2006,⁵³⁵ that although the Commission will take due account ‘of the need for the industry to recover its research and development costs, given the industry’s heavy dependence on innovation for its further competitiveness’, the aim was ‘to promote competition in innovation for patented medicines between the pharmaceutical producers, which has declined in Europe in the last decade, and to encourage inter-brand competition from generic substitutes after patent expiry’. Commissioner Kroes emphasised that this should ‘in time, contribute to ensuring a wider choice of both patented and generic pharmaceutical products to European patients at affordable prices’. Commissioner Kroes summed up that this was why ‘the Commission will give greater priority to competition in the generic sector in the immediate future.’⁵³⁶ Hence, while acknowledging the need for brand name drug manufacturers to recoup their R&D expenditure and to be rewarded for their innovative efforts, Commissioner Kroes also emphasizes that IP protection of medicines will, in some circumstances, come second to the promotion of competition from generic products, which drives down prices.⁵³⁷ Nevertheless, the Commission seems to expect that current enforcement activities will contribute to the *Lisbon Agenda* by stimulating innovation in the pharmaceutical sector whilst delivering on cost-containment through generic competition.⁵³⁸

⁵³¹ See Neelie Kroes, ‘*Towards a pro-active competition policy in favour of innovation*’, Speech at the conference Promoting Innovation and Competitiveness, A Transatlantic Dialogue; The Hague, The Netherlands; 27th & 28th April 2005. Available at http://europa.eu.int/comm/competition/speeches/text/sp2005_006_en.pdf

⁵³² See ‘*Consultation document on state aid for innovation*’, available at http://europa.eu.int/comm/competition/state_aid/others/action_plan/cdsai_en.pdf.

⁵³³ Id. pages 18 to 19.

⁵³⁴ Id.

⁵³⁵ Commissioner Neelie Kroes’ ‘*Reply to Oral Question put by the honourable Member of the European Parliament Mr von Boguslaw Sonik*’, (H-0459/06). Available at <http://www.futurdeleurope.parlament.gv.at/sides/getDoc.do?pubRef=-//EP//TEXT+CRE+20060613+ITEMS+DOC+XML+V0//EN&language=BG>. Visited on June 20, 2007.

⁵³⁶ Id.

⁵³⁷ Lawrance & Treacy, p.

⁵³⁸ De Souza, p. 41.

Others seem less convinced by the Commission's enforcement approach and argue that it risks having a chilling effect on innovation,⁵³⁹ something that in the long run will be far from consumer-friendly. In particular, they argue that the *AstraZeneca* decision raises the question of whether the competition authorities should intervene in this way in an industry, which is already heavily regulated, and which, furthermore, is not fully harmonized across the EC.⁵⁴⁰ Although it is clear that, in principle, pharmaceutical companies are subject to the competition rules, it may thus be questioned whether this decision goes too far and that the Commission is indeed pushing the boundaries of Article 82 EC.⁵⁴¹

Above all, however, it may be argued that the prevailing legal uncertainty surrounding the abuse of IPRs is likely to have a paralysing effect on the competitiveness of dominant undertakings at large. Considering also that decentralised enforcement of EC competition law can lead to very different outcomes from one Member State to the other, especially in complex IP and antitrust cases, there is a obvious need for the Commission (and the ECJ through its case law) to set clear *Guidelines* on the application of Article 82 EC to IPRs holders.⁵⁴²

Still, irrespective of any such guidelines, most commentators would agree that there is little doubt that the coming and much awaited judgment of the CFI in the *AstraZeneca* appeal case will shape the coming trends. Considering the economic importance of the undertaking involved and the effects that this judgment is bound to have on the pharmaceutical industry, it could set the tone of EC policy with respect to the antitrust and IP interface in the coming years. Until it does, the Commission will most likely continue to build on the inter-brand competition approach introduced in its *AstraZeneca* decision, and tackle various types of life cycle management strategies by research based pharmaceutical companies aimed at raising rivals' entry barriers.⁵⁴³

⁵³⁹ Although the Commission 'is at pains to point out that its decision is not intended to have a chilling effect on innovation', IPRs holders 'will see this as a further case which constrains their commercial freedom and increases uncertainty'. See Gibson Dunn, '*European Commission Raises Stakes in IP/Antitrust Battle*', June 16, 2005, available at <http://www.gibsondunn.com/practices/publications/detail/id/766/?pubItemId=7813>. Visited on July 5, 2007.

⁵⁴⁰ Arguably the regulatory framework already contains specific provisions designed to balance the competing interests of patentees and generic manufacturers so that additional competition intervention is not warranted. Note e.g. that the Canadian Competition Bureau in 2004 refused to intervene in relation to ever-greening practices on this ground. See Lawrance & Treacy, p. 8.

⁵⁴¹ Id.

⁵⁴² Eccles & Ferla, pp. 9-10.

⁵⁴³ See De Souza, p. 39 f.

9 Conclusive Comments

According to the US courts, both competition law and IP law ‘are aimed at encouraging innovation, industry and competition’.⁵⁴⁴ Similarly, the European Commission considers that there is no ‘inherent conflict between [IPRs] and the Community competition rules’.⁵⁴⁵ However, in practice, during much of this century IP law and antitrust law have coexisted uneasily, with a great deal of tension between the two bodies of law. While IP law provides for temporary legal monopolies, competition law aims at preventing monopolisation. The optimal balance between the two bodies of law must be found, so that innovation can be encouraged and anti-competitive behaviour prohibited, thereby safeguarding incentives for future inventions.

In this balancing process, much may be learned from experiences made across the Atlantic. Given that economic principles do not, unlike law, vary from country to country, there are often good reasons to examine competition cases brought elsewhere. There are, however, significant divergences in the underpinning philosophies of the US and EC regimes, and principles from one system should not be automatically applied to the other without good justification.⁵⁴⁶ That full convergence across the jurisdictions ought to be promoted is thus far from obvious. Policy makers, competition authorities and the courts on both sides of the Atlantic have therefore devoted much attention and effort to striking the appropriate balance within their own jurisdictions. In so doing they have nevertheless been influenced by case law from the other side of the Atlantic.⁵⁴⁷

In particular, the pharmaceutical industry has become a major target for antitrust investigations and litigation on both sides of the Atlantic. As a result of this increasing antitrust scrutiny from competition authorities, the options left to the research based pharmaceutical industry in the face of generic competition have dramatically reduced.⁵⁴⁸ Above all, it seems that the possibility to engage in aggressive litigation tactics has been restricted. For although a pharmaceutical undertaking in a dominant position, like any other dominant undertaking, has the right to protect its IPRs – in particular by initiating infringement proceedings – recent developments under US and

⁵⁴⁴ *Atari Games v Nintendo*, 897 F.2d at 1576 [14 USPQ2d 1034] (Fed Cir 1990).

⁵⁴⁵ Guidelines on Technology Transfer Agreements.

⁵⁴⁶ In other words ‘many valuable ideas for the interpretation of Community law can be derived from the discussions going on on the other side of the Atlantic and from the solutions found by the American courts. However, prudence must be counselled in transferring concepts and theories from one legal system to the other. There are substantial differences between the various elements going to make up US law and those going to make up Community law, with the result that not every problem confronting one of the two systems finds a counterpart in the other legal system.’ Advocate General Kirschner in *Tetra Pak Rausing SA v Commission* Case T-51/89 [1991] 4 CMLR at 343-44 in Furse, pp. 5-6.

⁵⁴⁷ Eccles & Ferla, p. 1.

⁵⁴⁸ Gunther & Breuvar, pp. 683-84.

Community law have lead to a situation where such legal action in exceptional circumstances may infringe Section 2 of the Sherman Act and Article 82 EC, provided it is clearly groundless and aims at eliminating a competitor.⁵⁴⁹

As a consequence of the Commission's *AstraZeneca* decision – the first EC case in relation to patent ever-greening – pharmaceutical companies holding a dominant position will need to take care that their conduct towards patent offices and medicinal authorities does not lead to foreclosure of competition by blocking or delaying market access for generic versions or parallel imports of their protected medicine.⁵⁵⁰ In particular, however, they will have to take care when it comes to patent infringement actions against competitors before national courts, as this issue is still clouded with uncertainty.

The fact that the Commission did not base any of its findings of abuse entirely on the *ITT Promedia* doctrine of vexatious litigation as an abuse of dominance does not diminish the significance of the fact that AZ's behaviour in this regard certainly contributed to the overall picture of abusive and anticompetitive acts. In this respect, the Decision seems to share common features with the US case law on *monopolizing schemes of infringement suits*. However, parallels may also be drawn to the US *Walker Process* and *Sham Litigation* doctrines. Though the Commission Decision lacks the weight to establish an EC version of the US doctrines on monopolization through vexatious litigation it is possible that the CFI in the appeal will add more authority to the arguably developing EC doctrine. Whether the *AstraZeneca appeal case* will set its mark as the leading case for 'vexatious patent litigation' as a possible independent abuse under Article 82 EC remains to be seen. Nevertheless, until the Community Courts have ruled on the matter, dominant pharmaceutical manufacturers will face significant legal uncertainties as far as patent infringement actions are concerned. Currently, neither the pursuit nor the settlement of patent infringement litigation appears an unfettered right.⁵⁵¹ Both the litigation and the resolution of infringement cases should therefore be undertaken with sensitivity toward antitrust risks.

⁵⁴⁹ Emmanuel Dieny, *The Pharmaceutical Industry and Competition Law between the Present and the Future*, E.C.L.R. 2007, 28(4), 223-232, at 225.

⁵⁵⁰ Lawrance & Treacy, p. 7. See also Gibson Dunn at <http://www.gibsondunn.com/practices/publications/detail/id/766/?pubItemId=7813>: 'Whilst it is encouraging that the EU continues to stress the importance of innovation and the need to reward innovation, this decision does not help that cause. It points to a policy where the antitrust analysis of whether or not any given behaviour is abusive should be assessed on a case-by-case basis. In the real world, that is a recipe for uncertainty and risk-taking'.

⁵⁵¹ Compare Deborah A. Coleman, Akron Law Review 2004, Intellectual Property Symposium Issue Article: *'Antitrust Issues in the Litigation and Settlement of Infringement Claims'*, 263, at 286.

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DG for Competition

Discussion Paper

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December 2005

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*Intellectual Property Rights and
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