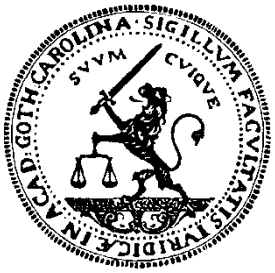

FACULTY OF LAW
Lund University

Aria Joze Zomorodian

Settlement Agreements in Patent Litigation

American lessons for a European context

Master thesis
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Supervisor
Hans Henrik Lidgard

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Contents

Summary

Patent settlement agreements lie in the intersection of patent rights and competition law. Patents are legal monopolies that are given to innovators as a reward for their findings, and competition law strives to limit the harm monopolies do to the market. Patent settlements in which the patent holder pays the generic manufacturer a not to market a competitive and possible infringing product, can either be seen as a legitimate way for a patentee to retain their legal monopoly, or as a way for a monopolist to share his monopoly earnings with a cartel member. In the US, Courts and authorities have had a head start of 20 years to achieve a balance between these views compared to Europe. Courts have allowed these settlements under the authorities protests. In Europe no case has gone before the court yet, but the European Commission regards these agreements with concern. This thesis engages in an inquiry into the nature of patent settlements and the legal framework that surrounds them, on both sides of the Atlantic. I will show that there are more similarities than differences between US antitrust and European competition law, reaching the conclusion that the use of settlements that include a value transfer from a patent holder and limits generic entry can be in conflict with competition policy, and therefore also art. 101 TFEU.

Sammanfattning

Förlikningsavtal i patenttvister ligger i brytpunkten mellan patenträtten och konkurrensrätten. Patent är ett lagligt monopol som ges som belöning till innovativa företag för väl utfört värv, medan konkurrensrätten strävar efter att begränsa eller förhindra den skada ett monopol utgör för marknaden. Förlikningsavtal med omvänd betalning kan antingen ses som ett legitimt sätt för en patentinnehavare att bibehålla sitt lagliga monopol, eller som ett sätt för två kartellmedlemmar att dela på monopolförtjänsten. I USA har man ett 20 år långt försprång att försöka hitta en balans i mellan dessa ibland motsatta intressen, jämfört med Europa. Amerikanska domstolar har tillåtit dessa förlikningsavtal, under myndigheternas ljudliga protester. I Europa har inget fall gått till domstol än, men EU Kommissionen betraktar dessa avtal med skepsis. Detta arbete undersöker förlikningsavtalens natur och regleringen som omger dem, på båda sidor Atlanten. Jag kommer visa på att det finns fler likheter än olikheter mellan amerikansk och europeisk konkurrensrätt, och komma till slutsatsen att förlikningsavtal som innehåller en värde överföring från patentinnehavaren och begränsar det generiska företagets marknadsintroduktion kan strida mot EU:s konkurrenspolicy, och därmed även art. 101 TFEU.

Preface

I would like to thank all those who have had the patience with me in the completion of this thesis. I cannot begin to express my gratitude to my mother, Zamir, and friends. Thank you for all your support in making this work possible. A special thank you to Hans Henrik Lidgard who has been more than patient, through this process.

Abbreviations

ANDA	Abbreviated New Drug Application
ECI	European Court of first Instance
ECJ	Court of Justice of the European Union
EPC	European Patent Convention
EPO	European Patent Office
FDA	United States Food and Drug Administration
FTC	US Federal Trade Commission
GC	General Court of the European Union
HCl	Hydrochloride
IPR	Intellectual Property Rights
MMA	Medicare Modernization Act of 2003
NCA	National Competition Agencies
NDA	New Drug Application
P.L.	Public Law
R&D	Research and Development
TRIPS	Trade-related aspects of Intellectual Property Rights
U.S.C.	United States Code

1 Introduction

Every year millions of euros and dollars are invested into research and development (R&D) of new pharmaceutical drugs, and only a few of the researched substances result in an end product. The end product is not only for the betterment of the art of medicine, but also a substantial investment for the researching pharmaceutical company. Patents are granted to secure these investments, and the company is rewarded exclusivity to its product, enabling it to fend off copycats for a set period of time. It is often argued that without patents, there would be less incentives for research and development, and that we would have even fewer pharmaceutical companies with R&D branches.

Once the patent life of a successful drug comes to an end, the market is permeated with generic versions, lowering the costs for consumers, insurance companies and in many cases governments. If a generic company is to release a version of a patented drug before the patent expires, this is seen as an infringement and the patent holder is within their rights to sue. If infringement can be shown, then the patent holder is entitled to damages.

1.1 Background to Patent Settlement Agreements

In recent years, concerns have been raised by the Commission of the European Union and by the Federal Trade Commission (FTC) in the US about what are called Reverse Payments, Exit Payments in settlement agreements or type B.II settlement agreements. In this paper when I discuss settlement agreements, it will be implied that these agreements contain reverse payments.

When a generic drug is released – or is announced to be released, especially before the expiration of the patent, the patent

holder sues for infringement. But before the case is brought before a court of law, the parties settle. The settlement includes a so-called reverse payment – a flow of value from the patent holding party to the infringing party, where the supposed infringer agrees to delay the release of its drug.

Both the FTC and the Commission of the European Union regard these settlements from an anti-trust perspective and are prone to deem them as unlawful, arguing that these settlements constitute market division. A conduct clearly illegal under the Sherman Act and Article 101 TFEU; to pay off possible competitors to refrain from entering the market, they argue. When a pharmaceutical patent is infringed, or allegedly infringed, the patent holder rushes to the courts to protect its rights covered by the patent. Patent infringement litigations are one of the most costly types of litigation before courts, and in the US more often resolved through settlements. These types of settlements are seldom open to public scrutiny, but since 2004, the FTC is sent a copy by default due to the potential antitrust issues they raise.

In Europe, a sectorial inquiry was launched in 2008 through dawn raids targeting the largest pharmaceutical companies in Europe, due to some delays in market introduction of generic pharmaceuticals. One of the concerns of the Director-General of Competition was the question of patent settlement agreements, and the “reverse payments” that could be found in some of these agreements. These payments are “reverse” in the sense that a patent holder agrees to grant economic compensation to a generic manufacturer, who in their turn agrees not to release an allegedly infringing product for a period of time, in the scope of a patent litigation settlement.

The controversy around these practices lay in the intersection of intellectual property rights and competition law – are these settlements an extension of a patentees right to exclude others (legal monopoly) or merely a way for two (potentially) competing

companies to divide the market horizontally, and thus infringe art. 101 TFEU?

Since the European experience of these settlement agreements is limited, one would be wise to look to the US for guidance. There have been several cases in the US covering these agreements, and the antitrust issues that might arise from them. The FTC is vigorously challenging these agreements in order to create a framework and guidelines of application concerning these agreements.

The outcomes of the US cases have not been uniform, showing that even with some experience in the matter; it is still a very complicated legal issue. The FTC fought for a *per se* illegality – that the mere fact that an agreement between potential competitors include a reverse payment clause and an agreement to delay entry should be enough to consider it illegal and an infringement of the Sherman Act. The approach that seems to be prevailing is assessing the agreements with a modified version of the *rule of reason*, where the courts consider the agreement in its legal and economic context, weighing the antitrust issues, against the exclusive qualities of patents, with the right to litigate and settle a dispute out of court. It is the judgments of the Circuit Courts we have to rely on, since certiorari to the Supreme Court has until now been denied.

Another important aspect that follows the would-be-collision between Intellectual Property Rights (IPR) and antitrust provisions is the matter of legal economics. To fully analyze these agreements and their restraint on competition, it is important to view these agreements in the light of the legal economics of these fields. Because if law is a reflection of policy, then what is protected by law, and why?

1.2 Purpose and research questions

Since settlements with reverse payments are viewed as problematic on both sides of the Atlantic, and no judgment has yet been rendered in a European court, I want to see what their legal status is in a European context. The question I am interested in is whether *settlement agreements with reverse payments prevent, restrict or distort competition under article 101 TFEU*, and if so, are they to be seen as *per se* violations of competition law?

1.3 Material and Methodology

To answer the question I will research the balance between the rights awarded to a patent holder under patent laws, with the need for safeguarding healthy competition on the pharmaceutical market. To do this, I will use *traditional dogmatic legal method* to clarify the legal systems; to account for current law and its application in the fields of competition and patent law on both sides of the Atlantic. The same method is used when accounting for the American case law on which conclusions will be drawn for the European legal frame.

I will also be using *comparative legal method*[1] to contrast and highlight the similarities and differences of American and European Competition law and patent law, to make and point out relevant observations when drawing conclusions based on American case law in a European context.

The close ties between law and policy will also be accounted for, as well as some explanations of the pharmaceutical market using an economic perspective in the analysis, but not using a true *legal economic method*. This is to show the close ties between antitrust/patent law and economics, both in results and in policy aims. Economics is a useful tool to understand and explain the mechanics of settlements in patent infringement cases, and the impact patents

[1] An Introduction to Comparitive Law, Zweigert and Kötz 1998

have on the pharmaceutical market. Economic perspective is also essential in understanding competition policy aims and what competition law is to protect.

The doctrine on this subject is limited to articles in legal and economic journals, due to the lack of handbooks and the novel nature of the subject.

1.4 Delimitations

Settlements in patent litigation and reverse payments can be found in many legal fields, and I have chosen to investigate only litigations and settlements between pharmaceutical patent holders and generic pharmaceutical companies. I will not treat any vexatious litigation because that is an entirely another field of study, nor will the European Patent system and its details be given too much space.

I will also leave the ever-recoiling common law details in American case law without consideration, due to lack of space. Most judgments and conclusions that are made by American courts are based on precedents, albeit powerful as tools, they are of little interest for us in this paper.

I will barely touch upon the intricate and difficult tasks of defining market shares, because I will assume the market share for a medical product to be very narrow, a prescription drug can only be substituted with a bioequivalent.

TRIPS, the treaty on trade of intellectual property, although essential for the international use of patents rights, will be given no room. Many barriers to enter the pharmaceutical market can exist, and pharmaceuticals can use many strategies to evergreen a patent, but I have not taken these into consideration in this thesis.

1.5 Outline

In Chapter 2, I will start with an account for the legal framework that surrounds the subject matter of this thesis, starting with the American antitrust and patent laws, and then continuing with the European counterparts.

When the reader has been acquainted with the legal aspects of the settlement agreements, a deep study of five chosen cases from the American legal system will be abstracted in Chapter 3, followed by an analysis.

Chapter 4 of the thesis will discuss the findings from an economic perspective, explaining the economic theories that governs EC policy to better understand how to treat these settlements, before drawing final conclusions, that are presented in Chapter 5.

2 Legal framework

Historically cartels have been seen as a natural economic entity in Europe,[2] so the origins of antitrust provisions stem from American distrust of both big business and a probing government.[3] The Sherman Antitrust Act 15 U.S.C. (hereafter The Sherman Act) was constructed as a safeguard for those who feared to be overrun by monopolies, but also those who feared too much governmental involvement on the market.

After the Second World War, American Antitrust was exported, first to occupied Japan, and later to Europe and the Coal and Steal Community that would later become EC and the EU, keeping much of its ancestry. One might see a inherit paradox in Competition law – where we have a policy to control and interfere with and on the market, so it can operate freely.[4] In Europe the main objective for the competition provisions are to promote *economic efficiency*[5] and consumer welfare. These objectives that are best explained in economic terms will be discussed further in the analysis in chapter 4.

IPR and patent law, on the other hand, create a legal monopoly and due to their legal status these monopolies are exempted from antitrust scrutiny.[6] Patents have been granted all through history, dating from Grecian times to the present, as a way to promote and increase innovation and consumer welfare. Allowing the inventor to reap the fruits of their labors, and spreading new technology for the betterment of all.[7]

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[2] The Evolution of European Competition Law, Ulrich 2006 p 25
[3] Ibid. p 19
[4] EC Competition Law, Jones and Sufrin 2008 p 2
[5] Ibid. p 18
[6] Lärobok i immaterialrätt,, Levin 2011 p 24
[7] Patents, Copyrights and Trademarks, Foster and Shook 1993 p 3

Even though both these legal areas seek to augment economic efficiency through a more effective competition and innovation in the long term, they can be perceived to clash in the short term.[8] As stated above, the European Competition provisions have their origins in the American Antitrust provisions, The Sherman Act dating 1890. Although an evolution of Antitrust and Competition law cannot be denied, I intend to start the overview of applicable law with American antitrust, and then continue with its European counterpart in article 101 TFEU.

2.1 American Law, Policy and Market structure

2.1.1 The Sherman Act 15 U.S.C.

Section 1.

Trusts, etc., in restraint of trade illegal; penalty

Every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal. Every person who shall make any contract or engage in any combination or conspiracy hereby declared to be illegal shall be deemed guilty of a felony, and, on conviction thereof, shall be punished by fine not exceeding $10,000,000 if a corporation, or, if any other person, $350,000, or by imprisonment not exceeding three years, or by both said punishments, in the discretion of the court.

As in most aspects of Common law statutes, the legal text is viewed and interpreted only in the light of case law.

The wording prohibits "*every contract*… *in restraint of trade*" which would mean that even an agreement to form a partnership would be seen as a restraint on trade, since the newly formed partnership

[8]ABA Section of Antitrust Law, Intellectual Property and Antitrust Handbook, 2007 p 1

would not be competing.[9] Luckily much has happened in this area, since the rule of reason- analysis was launched by the Supreme Court as early as in 1911, in Standard Oil Co. v. United States.[10]
In the past some conduct has been deemed as per se illegal by the courts and listed in a catalogue but that view has undergone a change in the recent years.

Now the courts see the application of a per se analysis as a truncated rule of reason analysis.[11] Although agreements that have a "predictable and pernicious anticompetitive effect, and… limited potential for precompetitive benefit"[12] are still seen as per se unlawful, most contracts are subject to the rule of reason analysis,[13] where the "pros and cons" of an agreement are weighed against the results and effects on trade. There is no precise formula but the courts use a balance test that focuses on:

1. The effect of the restraint on competition, weighing in the defendant's market shares,
2. The intent of the defendant,
3. legitimate business justifications and pro-competitive effects.[14]

The Sherman Act prohibits restraints on trade, but State Oil v. Khan[15] acknowledges that Congress intention is to ban *unreasonable* restraints only, that is a restraint that has an adverse effect on or "*impairs competition*",[16] established either as a "naked restraint"

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[9] Monopsony in Law and Economics, Blair and Harrison 2010 p 17
[10] Standard Oil Co. of New Jersey v. United States, 221 U. S. 1 (1911) p 62
"/…/ it becomes obvious that the criteria to be resorted to in any given case for the purpose of ascertaining whether violations of the section have been committed is the rule of reason /…/.
[11] ABA Antitrust Section, Monograph No. 23 The Rule of Reason 1999 Hartley p 100
[12] State Oil v Khan 522 US 3, 10 (1997)
[13] Texaco Inc. v. Dagher, 547 U.S. 1, 5 (2006) "*It is not per se illegal under §1 of the Sherman Act for a lawful, economically integrated joint venture to set the prices at which it sells its products."*
[14] ABA Antitrust section, Monograph No. 23 The Rule of Reason, 1999 Hartley p 102
[15] State Oil v. Khan 522 US 3, 10 (1997)
[16] Chicago Board of Trade v. United States 246 US

(price fixing etc.), actual effect on competition or restraint that creates or enhances market power.[17]

2.1.2 U.S. Patents

U.S. patent laws are codified in Article I, Section 8 of the U.S. Constitution, which states that Congress shall have the 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.[18] "There are three basic types of patents: utility, plant, and design patents. Utility patents generally have a term of 20 years from the date on which the application for the patent was filed. Utility patents are divided into three basic categories: chemical, electrical and mechanical.

Pharmaceutical patents are a subset of chemical patents and are issued over four different categories: drug substance, method of use, formulation, and process. Drug substance patents cover the compound or active ingredient in the drug product Method of use patents cover the use of the product to treat certain health problems. Formulation patents cover the physical composition or delivery mechanism of the drug product, such as an extended release tablet or capsule. Process patents generally cover the procedure used to make the active ingredient. To be patentable, an invention must be new and useful, as well as non-obvious. The Patent Office determines novelty by searching prior patents and publications.

Before the Hatch-Waxman act a generic company could not perform clinical trials on a patented drug before the patent expiration. Such use of a patented drug would be seen as a commercial use and an infringement of the patent.

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[17] ABA Antitrust Section, Monograph No. 23 The Rule of Reason, 1999 Hartley p 104
[18] Generic Drug Entry Prior to Patent Expiration: An FTC Study, 2002

2.1.3 The Hatch-Waxman Act

When the Hatch-Waxman act was passed in 1984 it sought to create a balance between protecting innovation and facilitate for generics to enter the market and the increase in competition.[19] It facilitates entry by letting generic companies that seek Federal Drug Administration (FDA) approval to use and rely on the clinical trials performed by the original company.

A special exemption from patent law is also given: the generic company can manufacture and test drugs in spite the existence of a patent, without facing damages. As a counter measure, branded companies are awarded more generous patent life with extensions to compensate some of the "useful" time consumed during clinical trials.

A generic files an Abbreviated New Drug Application (ANDA) in which they must provide one of four certifications;

I. No such patent information exists in the orange book (where all patented drugs are listed).
II. The patent has expired.
III. The patent will expire before the marketing of the generic drug.
IV. The patent is invalid, or will not be infringed by the generic.

When the ANDA with a paragraph IV certification is filed, the patent holder is notified, and usually sues for infringement within the 45-day time frame. This suit triggers a 30-month stay, under which the FDA is prohibited from approving the ANDA, or any other ANDA concerning the patent in issue.

As an incentive for generics to challenge existing patents, the first ANDA with a paragraph IV certification filer is given a 180-day exclusivity period beginning when the generic product is

[19] Reverse payments in Hatch-Waxman Cases and the Continuing Antitrust-Patent battle, K. Mcdonald and J. Mauk

marketed, during which the FDA cannot approve another ANDA. In the beginning, only the first filer had the right to the 180-day duopoly period, but that right can be forfeited after 2003[20] and gained by another filer.

The patent settlement agreements at hand all arise from paragraph IV certification ANDAs. Patent holders are faced with a new type of infringement, where their patent has been infringed, but no damages can be granted since no infringing sales have occurred. Thus the risk is eschewed- patent holders stand to loose their monopoly, where the generic competitor risks "only" litigation costs. This situation has lead to so called pay for delay settlement agreements, where the parties eliminate the risk of litigation by settling, and transferring value from the patent holder to the generic company.

2.1.4 Federal Trade Commission and US Policy

The Federal Trade Commission is tasked with the overview and enforcement of anti trust law in the US. They have vigorously tried to put an end to "pay for delay settlements" since 1998,[21] finding these agreements a great threat to the national health system. The FTC appreciates that settlement agreements of this type costs consumers, and their insurance policies "between $3.5 billion and $12 billion per year."[22] Generic medicines are essential in containment of the cost of elderly care for the government, since the elderly make up 25% of the prescription drug market in the US.[23]

The Hatch-Waxman act was passed to facilitate the entry of generic medicines on the American market. Congress sought

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[20] P.L. 108-173 Medicare Prescription Drug, Improvement, and Modernization Act of 2003
[21] Prepared statement of the FTC before the subcommittee on courts and competition policy on judiciary united states house of representatives June 3 2009 http://www.ftc.gov/os/2009/06/P859910payfordelay.pdf
[22] Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions http://www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf
[23] Brief of Amici curiae, American Antitrust Institute http://www.ftc.gov/os/2011/05/110518amicusbrief.pdf

to strike a balance between the public interest in encouraging innovation and their interest in competition, claims the FTC.

The FTC Study of 2002

The FTC launched a study[24] (FTC Study) in April 2001 to monitor generic entry prior to patent expiration, and especially settlement agreements. One study cited in the FTC Study found that the average price of a generic prescription drug was about half of the brand name prescription drug. Generics created somewhere between $8 billion and $10 billion in savings for consumers in 1994.

Overall approximates were that average drug prices declined around 20% within 2 years after generic entry, and that one can see a decline in both brand name prices and generic prices when more than one generic are competing. Prices kept falling until at least a fifth generic firm enters the market. The scope of the FTC Study was restricted to the competitive circumstances surrounding ANDA notices containing paragraph IV certifications between January 1992 and January 2001.

As a whole 6% (483 ANDAs relate to 130 New Drug Applications) of all applications in the FTC study contained paragraph IV certifications, but the trend has been increasing. 1984-1989 only 2% raised patent issues, in the 1990s 12% and in the last two years of the examination 20%.[25]

75% of these ANDA applications where followed by a patent infringement suit, 20 of these litigations resulted in settlements. Of all patent infringement cases where a judgment has been rendered, generics prevailed in 73%; 14 cases where found the ANDA to be non-infringing on the patent, and 11 cases of patent invalidation.

9 settlements ending litigation contained “reverse payments”, with the range from $1.75 to $132.5 million. 2 did not fit these typical types of settlements, 2 settlements allowed the generic

[24] Generic Drug Entry Prior to Patent Expiration: An FTC Study (FTC Study of 2002)
[25] FTC Study of 2002 p 10

to distribute the brand name product as a generic under the originators NDA, and the remaining 7 contained licenses (solving infringement issues) from the originator to generic to launch the generic product before patent expiration under the ANDA. 6 of these settlement including licenses or supply agreements where entered into in 2000-2001.

The agreements with payments from the originator to the generic also prohibited the generic from manufacturing, purchasing, distributing etc. any form of the generic product. 4 of these patents where so called formulation, or method use type of patents, and in these instances the agreements also prohibited the generic to launch any other form of the brand name product. In almost all of the agreements, the generic also agreed not to aid or facilitate for another generic to market a product before patent expiration.

After this study, the FTC recommended to Congress to pass a law where pharmaceutical companies are required to file these types of agreements with the FTC, to put an end to this possibility of short-term protection from competition.[26] Congress passed the Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA) that requires pharmaceutical companies to do just that; file certain agreements with the FTC and the Department of Justice (DOJ). FTC scrutiny and actions against these types of agreements deterred companies from concluding such agreements from April 1999 to 2004, with the culmination in the Cardizem verdict (see section 3.1.1) deeming such agreements a *per se* violation of the Sherman Act. In 2005 the verdicts in Schering-Plough (3.2.1) and Tamoxifen (3.2.2) opened up the possibility for the use of these agreements, and the FTC started receiving filings according to the MMA.

[26] Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions p 1

In January 2010 the FTC released a summary report[27] with findings from the fiscal years 2004-2009. A Total of 218 settlement agreements where filed with the FTC, and the lion's share, 70% did not involve a payment from originator to generic with subsequent market delay. Those agreements containing compensation from originator to generic, postponed generic entry with 17 months longer than agreements without compensation.

2.2 European Law, Policy and Market structure

2.2.1 Article 101 TFEU

(Ex Article 81 TEC)

1. The following shall be prohibited as incompatible with the internal market: all agreements between undertakings, decisions by associations of undertakings and concerted practices which may affect trade between Member States and which have as their object or effect the prevention, restriction or distortion of competition within the internal market, and in particular those which:

(a) directly or indirectly fix purchase or selling prices or any other trading conditions;

(b) limit or control production, markets, technical development, or investment;

(c) share markets or sources of supply;

(d) apply dissimilar conditions to equivalent transactions with other trading parties, thereby placing them at a competitive disadvantage;

(e) make 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.

[27] Ibid.

2. Any agreements or decisions prohibited pursuant to this Article shall be automatically void.

3. The provisions of paragraph 1 may, however, be declared inapplicable in the case of:

- any agreement or category of agreements between undertakings,

- any decision or category of decisions by associations of undertakings,

- any concerted practice or category of concerted practices,

which contributes to improving the production or distribution of goods or to promoting technical or economic progress, while allowing consumers a fair share of the resulting benefit, and which does not:

(a) impose on the undertakings concerned restrictions which are not indispensable to the attainment of these objectives;

(b) afford such undertakings the possibility of eliminating competition in respect of a substantial part of the products in question.

Historically, one of the main objectives of European competition law has been the creation of a single market, to remove barriers and create a truly unified market. In this single market European competition law seeks to promote economic efficiency as a whole and consumer benefit in particular through prohibition against anti-competitive agreements, anticompetitive behavior of large companies and by controlling mergers of companies to avoid anti-competitive market structures.[28]

The cartel prohibition found above in art. 101.1 TFEU bans all agreements that have as objective or effect to distort competition on the common market. The term *undertaking* is used broadly including anyone "engaged in economic activity"[29] and the agreement must be entered into between two different economic entities. Also the term agreement is used widely; it can mean written,

[28]The European Union: Economics and Policies, Al-Agraa and Ardy pg 197

[29] C-41/90 Hoefner v Macroton GmbH 1991

oral or tacit. In this first paragraph some consideration is given to economical and industry specific conditions when deciding whether an agreement is illegal but these considerations are predominately considered under the third paragraph.

The collusive agreements (or parts of where possible) are voided in the second paragraph, if not exempted by the third paragraph, and for those exemptions that can occur, the Commission has had a series of Block exemptions as guidelines. Since May 2004 and the directive 1/2003[30] the National Competition Agencies (NCA) and courts are also allowed to use art. 101(3) in exempting agreements from nullity.

An agreement can also fall outside the scope of article 101 if the effect on the common market is insignificant, and the Commission issues *de minimis*-notices as guidelines on the size of undertakings automatically fall out of scope.[31] Ordoliberal (more explained in chapter 5) concerns of economic concentration and efficiency with distributive justice is fulfilled with the test brought about in the third paragraph; exemption from nullity can be granted if the agreement can increase efficiency and if that increase is passed on to consumers.[32]

According to the CFI in Métropole,[33] the exemption from nullity in art 101(3) TFEU is divided into four parts after one establishes the anticompetitive aspects of the agreement according to article 81(1).[34]

1. Pro-competitive objectives and effects must be established.
2. One must show that consumers attain a fair share of these objectives

[30] Regulation 1/2003 in the implementation of the rules of competition laid down in art. 81 and 82 of the treaty, 2003 OJ L1/1
[31] EC Competition Law, Jones and Sufrin p 183
[32] EC Competition Law, Sufrin and Jones p 215
[33] T-528/93 Métropole Télévision SA v Commission 1996
[34] EC Competition Law, Jones and Sufrin p 237

3. The agreements and anti-competitive clauses are necessary in obtaining the objectives.
4. Competition is not completely eradicated by this agreement.

2.2.2 European Patents

The European Patent Office creates and regulates what are called European Patents under the provisions of the European Patent Convention (EPC), although contracting members are not limited to EU member states only.[35] European patents, according to article 64 EPC, enjoy the same rights as national patents in the contracting states. This is not a strict *patent*, but merely a more cost effective way of applying for many national patents at one time.

In Europe, there existed only four possibilities for exemption from the patentees exclusive right to a patented product. These were: 1. non commercial use 2. patent right had been consumed within the common market 3. further experiments with the invention and 4. preparation of the drug in a pharmacy according to a physicians prescription. Generic testing did not fall under the experiment exemption, since clinical trials for generics to get market approval were not seen as experimental since they merely repeated what had already been done for a future commercial use.[36] To amend this, the directive 2004/27/EG was passed in 2003.

One of the objectives of directive was to facilitate entry of generic pharmaceuticals on the common market, by removing some of the obstacles that existed. The directive added a fifth possibility in the exemptions mentioned above, dedicated for generic companies. Clinical trials by generic companies on patented drugs are now permitted, and under article 10 (2b) the generic drug can "free ride" the clinical trials (as allowed under Hatch Waxman) of a patented drug if bioequivalence is proven- the so-called Bolar-

[35] Lärobok i immaterialrätt, Levin 2011 p 54
[36] Läkemedelspatent – Patent på läkemedel i Europa ur ett rättsvetenskapligt och rättsekonomiskt perspektiv, Domeij 1998 p 464

provision.[37] So now, a generic can get a market authorization for a bioequivalent drug, before the patent has expired ready to market at expiration, where they before had to carry out their testing in countries where the patent did not exist or had lapsed[38] or wait until patent expiration in Europe.

2.2.3 Sectorial Inquiry and the European Commission

The Commission of the European Union emphasizes in the Executive Summary of the Pharmaceutical inquiry Report (the Summary Report) the importance of supplying European patients with effective and affordable medicines, but also maintaining a European business climate that promotes and stimulates research. Key here is, not only innovation says the Summary Report, but also intellectual property rights to spur innovation. At the same time, the public budgets are under heavy constraints, thus the need for generic competition is greatly needed to facilitate access of affordable medicine for consumers. Generic medicine help limiting health expenses in the European Union, and policy should move towards facilitating speedy generic entry after patent expiration.

In January 2008 an inquiry was launched in the pharmaceutical sector to investigate the whether competition was being restricted, due to decline in innovation, resulting in fewer novel products on the market, and delays of generic entry.[39]

The inquiry sought foremost to investigate company behavior and competition between originator companies and generic counterparts to better understand the pharmaceutical sector, not to intervene. The scope of the inquiry included companies with 80% of the relevant turnover in the EU, 43 originator and 27 generic

[37] Lärobok i Immaterialrätt, Levin 2011 p 325
[38] Executive summary of the Pharmaceutical Inquiry Report p 4
http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/communication_en.pdf
[39] Commission Decision of 15 January 2008, COMP/D2/39.514 p 3

companies, limiting products to medicines for human use within the 27 member states and the time limitation was from 2000 to 2007.

2.2.4 The European Pharmaceutical Market structure and the impact of generic entry.

The inquiry found that 50% of medicines subject to scrutiny were faced with generic competition within a year after losing exclusivity, in average within 7 months. On average the generic price was 25% lower than the originator companies product on entry, and less than 40% after two years, when also the originator's price drop. The generic covers 30% of the market shares after the first year and increases their share to 45% after two. On average the health system savings are 20% after year 1, and 25% after year 2. Savings could have been even higher if generic market entry had been possible immediately after loss of exclusivity period.

One of the reasons why generic entry was delayed was found to be Patent settlement agreements. In total 698 cases of litigation was reported in the investigation, and of these 223 cases were settled. 149 cases rendered final judgments and although mostly initiated by the innovating companies, 62% of the judgments where in the generic's favor.

The settlement agreements found in the inquiry covered 49 medicines, of which 31 where best selling drugs that lost exclusivity between 2000 and 2007. 50% of these settlements restricted the generic companies market entry and a significant number also included some kind of value transfer from the originator to the generic, in 20 cases being direct payments, totaling ¬200 million.

The Summary Report finds these agreements that restrict market entry of the generic and includes a value transfer from the originator company cause for concern in their conclusion. They decide to carry out a special focused monitoring of settlements "with

a potential to adversely affect European consumers."[40] These focused monitoring exercises resulted in two reports.

Reports in the Monitoring of Patent Settlements 1[41] and 2[42]

The main objective of the Monitoring Reports were to better understand and identify any agreements between originator companies and generic companies that delay generic entry to the "detriment of the European consumer"[43] thus potentially violating competition law. Settlement agreements are defined as agreements that settle actual or potential patent related litigation, where no final judgment had been passed. Although settlements are generally accepted, according to the Monitoring Reports, and have some positive impact on society (i.e. time and cost savings for courts and administrative bodies) these settlements can be problematic if they impose restrictions beyond the exclusionary zone of the patent, that is to say beyond the patent claim.

In the Monitoring Reports the settlement agreements are divided into categories that define the potential harm to competition, see diagram[44] below.

Settlements of type A are unproblematic from a competition point of view, and so are settlements of type B.I unless the settlement is on a patent that does not meet the patentability criteria and the patent holder is in bad faith. The settlements of type B.II are typically the ones that would attract the highest degree of antitrust scrutiny.

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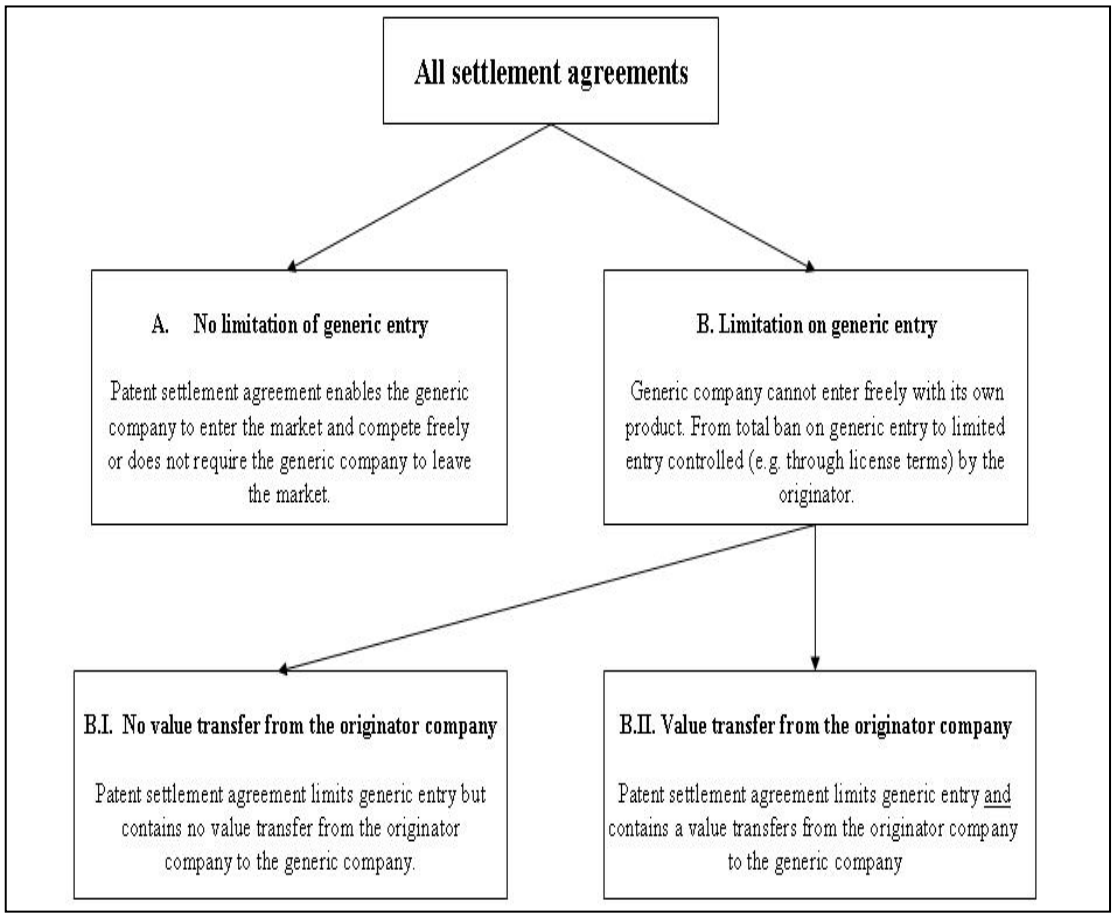
[40] Executive Summary Report p 20

[41] 1st Report on the Monitoring of Patent Settlements, July 5 2010 http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/patent_settlements_report1.pdf

[42] 2nd Report on the Monitoring of Patent Settlements, July 2011 http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/patent_settlements_report2.pdf

[43] 1st Monitoring Report p 1

[44] 2nd Monitoring Report p 4



Results of the 1st Monitoring Exercise 2008/2009

This exercise covers 41 originator and 45 generic companies in the period July 08 to December 09. In total 93 settlements had been entered into by 39% of the originator and 47% of the generic companies.

53 of these where type A settlements, 31 of type B.I and 9 of the more problematic type B.II. The value transferred to the generic took different forms; two agreements included payments covering damages and legal fees, one included a side deal. One agreement included payments and licensing agreement, five cases included supply, licensing and distribution clauses. Compared to the findings in the Sector Inquiry, the payments and value transfers that where found in the Monitoring Exercise were relatively small, ¬1 million compared to ¬200 million.

Even though the decrease in amounts and frequency of type B.II settlements; 10% of all settlements during the monitoring

period compared to 22% during 2000-2007, it was decided to continue the monitoring for another year.

Results of the 2nd Monitoring Exercise 2010

This exercise covers 59 originator and 70 generic companies, where 22% of the originators and 23% of the generics concluded patent settlements, in total amounting to 89 individual settlements for the year 2010.

The type A settlements where the largest group also in the 2nd Monitoring Exercise, in total 54 settlements. 32 settlements where of the type B.I, leaving 3 potentially collusive settlements of type B.II. The value transferred in these cases from the originator to the generic took two forms; one agreement included a direct payment, the other two included licensing agreements with the originator.

The Commission notes that, even though the numbers of type B.II settlements have decreased substantially (only 3% in 2010), companies have not been deterred from entering settlement agreements in general.

The unproblematic settlement agreements have increased from 26% to 36%. To find out whether these trends are passing, or merely explained by the sector's awareness that it is being scrutinized, the monitoring will continue for another year.

In spite the fact that the Commission sees the decline in patent settlements as "good news for consumers who will benefit from cheaper pharmaceuticals"[45], the sector isn't out of the woods yet.

As a result of the Monitoring Exercises, the Commission has opened proceedings against originator pharmaceutical companies and generic companies, wishing to scrutinize the potentially collusive settlement agreements, of type B.II that have been entered into. Some examples are proceedings against Les

[45] EC Press Release of 6 July 2011, Antitrust, IP/11/840

Laboratoires Servier[46] and several generics in July 2009, Lundbeck[47] in January 2010, Cephalon and Teva[48] in April 2011 and Johnson&Johnson and Novartis[49] in October 2011.

Little is known about these proceedings and as the communiqué says "[t]here is no legal deadline to complete inquiries into anticompetitive conduct[50]." The duration is very dependent on many factors; complexity of the affair, co-operation of the undertakings under investigation etc.

To better understand, and maybe predict the outcome these proceedings, I have looked at some cases in American courts. The Federal Trade Commission has during the past 20 years vigorously tried to ban settlement agreements of type B.II, with mixed results.

[46] EC Memo of July 2009, MEMO/09/322
[47] EC Press Release of 7 January 2010, Antitrust, IP/10/8
[48] EC Press Release 28 April 2001,1 Antitrust, IP/11/511
[49] EC Press Release of 21 October 2011, Antitrust, IP/11/1228
[50] EC Press Release of 28 April 2011, Antitrust, IP/11/511

3 American Case Law

As stated above, the American legal system has had an earlier opportunity to deal with these types of cases, among other things due to the fact that Hatch-Waxman was passed in the mid 1980s, while European generics had to wait until 2004 for the Bolar-provision to give them the same opportunity to “piggy back ride” on the clinical trials of an originator before marketing a bioequivalent generic.

Below, five cases from American Appellate Courts are discussed in detail, not only to show the complexity of the cases, but also how the verdict has changed in the different instances, although policy has remained the same.

Before analyzing the cases one must bear in mind the differences between European and American antitrust law and enforcement. The FTC and the DOJ, the enforcement bodies of American antitrust, bring antitrust cases before federal courts. They primarily have the role of prosecutors, but also some carry some weight in shaping the application of law.[51]

The European competition counterpart, the Commission of the European Union, rules by giving binding decisions, acting instantaneously as prosecutor and judge. In the US private antitrust litigation is common, and creates a development, case by case in courts, where in Europe the administrative authority creates the development. The Court of Justice of the European Union (ECJ) and The General Court of the European Union (GC) (ex. The Court of first Instance, CFI) only reviews the legality of the Commissions decisions.

[51] EC Competition Law, Jones and Sufrin p 21

3.1 *Per Se* ban of Settlement Agreements

Our discussion of case law begins with Cardizem, where settlement agreements with reverse payments were seen as per se violations of the Sherman Act. This was a great success for the FTC, who had had varied results in lesser courts up until this verdict. The verdict effectively put an end to settlement agreements and in the succeeding year 2004 no agreements were filed with the FTC.

3.1.1 In Re Cardizem CD Antitrust Litigation

June 13 2003

Question

The question posed to the Circuit Court was whether the settlement agreement between the parties was to be viewed as a horizontal market allocation agreement and thus deemed as per se illegal under the Sherman Act?

Background

Hoescht Marion Roussel Inc. (HMR) was the manufacturer and marketed Cardizem CD, with the active ingredient dilitiazem hydrochloride. The patent for the active ingredient was to expire in November 1992. In September 1995 Andrx Pharmaceuticals Inc. (Andrx) filed an ANDA seeking to market a generic form of Cardizem, in December the same year they added a paragraph IV certification to their application with the FDA, being the first generic applicant.

In November 1995 HMR acquired a license to a patent covering Cardizem CDs “dissolution profile”, US patent 5,470,584 (‘584 patent). The dissolution profile claimed by the patent was 0-45% of the total dilitiazem HCl released within 18h.

In January 1996 HMR sues Andrx in District court for patent infringement, claiming that a generic version would infringe the newly acquired ‘584 patent, seeking neither damages nor

preliminary injunction, but triggering the 30 month stay where the FDA could not approve the ANDA.

Andrx amended their ANDA and specified the dissolution rate to be not less than 55% during 18h. On September 15 1997 FDA approved the ANDA, making the generic version marketable in July 1998 (after 30 month stay) or if Andrx received court ruling that generic product did not infringe the ‘584 patent.

The settlement agreement was entered into on September 24 1997, nine days later than the FDA’s tentative approval of Andrx ANDA. On July 8 1998 the 30-month stay expired, and the FDA issued a final approval of the ANDA the next day, when also HMR started their payments to Andrx, who failed to bring their generic to the market.

In September 1998 Andrx sought approval for a reformulated version of a generic, in a supplement to the filed ANDA. In June 1999 the FDA approved the reformulated product, and the parties settled the infringement case and terminated the agreement on the same day. Later that month, Andrx released the generic version and enjoyed the 180-day exclusivity period, and has since captured a large portion of the market.

The Settlement Agreement

In the agreement Andrx agreed not to market a bioequivalent or generic version of Cardizem until 1) they received a favorable final and un-appealable ruling in the infringement case 2) HMR and Andrx entered into a licensing agreement or 3) HMR entered into a licensing agreement with someone else.

Furthermore Andrx agreed not to relinquish their rights under the ANDA provisions, and to dismiss their anti trust counterclaims. In return they would receive yearly payments of $40 million dollar, beginning on the day final FDA approval was granted to Andrx. HMR also agreed to pay Andrx $100 million dollar per year (less interim payments) if a final court ruling deemed the patent not

infringed, HMR dismissed the infringement case, or HMR failed to appeal an appealable judgment. Total amount paid until the settlement in June 1999 from HMR to Andrx was $89,83 million.

3.1.2 Court Decision

The court starts by stating that the rule of reason governs most evaluations of unreasonable restraints against competition, in Sec. 1 Sherman Act, but points out that some restraints are unlawful on their face – *per se* illegal. This is due to the predictability in their anti-competitive nature, and the very limited potential for antitrust benefit. One can use the per se rule, if one with confidence can assume that the rule of reason will condemn it.

The Court then continues by claiming that the Supreme Court has used the per se ban against horizontal restraints, price fixing or market allocations being classic examples. In the case at hand, HMR guaranteed its only competitor $10 million/quarter to stay off the market after they had obtained FDA approval for their generic version of Cardizem CD. Not only did the agreement delay the entry of Andrx generic version, but also, by retaining the 180 day exclusivity period, other competitors where also kept off the market.

The court concludes that the settlement agreement in its “core” is an agreement between horizontal competitors, to eliminate competition on the Cardizem CD market throughout the United States, and is a classic example of a per se illegal restraint of trade. This settlement agreement cannot be seen as a way for HMR to exert the natural monopoly that arises from a patent, since it’s a completely different thing to “bolster the patent’s effectiveness” in inhibiting competitors to enter the market by paying $40 million per year. The settlement also restrained Andrx from marketing, bioequivalent and non-infringing versions of Cardizem, thus extending the settlement to versions not at issue in the litigation.

3.2 The Eleventh Circuit's solution

The success for the FTC was short lived. The Eleventh Circuit rejected the idea of settlement agreements being per se violations, but also the rule of reason analysis. According to the Court, these tools were to find an element that put a restrain on trade, but that element is already present in cases where patents are involved. The court adopted their own tools for reviewing these cases.

3.2.1 Valley Drug Company, Louisiana Wholesale Drug Company INC. et al versus Geneva Pharmaceuticals INC., Abbott Laboratories,

September 15, 2003

Question

Were the district courts correct in assessing two patent settlement agreements to be per se violations of §1 Sherman Act?

The two settlements between Abbott and possible competitors Geneva and Zenith are the base for this judgment.

Background

Abbott is the manufacturer of Hytrin, a successful brand name compound used to treat hypertension and prostate enlargement. The active ingredient is dihydrate terazosin hydrochloride, and Abbott obtained FDA approval for its NDA for Hytrin in 1987.

Since then Abbott have held a number of patents concerning terazosin hydrochloride over the years for various forms of the compound.

Geneva filed four paragraph-IV certification ANDAs based on Hytrin between the years 1993 and 1996. Abbott subsequently filed for infringement, triggering the 30-month stay of FDA approval of Geneva's ANDAs. In April 1996 two additional ANDAS were filed, one capsule form and one tablet form of terazosin

hydrochloride. Abbott sued, arguing that the tablet form terazosin product from Geneva infringed Abbotts patent 5,504,207. Geneva admits infringement, but contests the patents validity. Abbott does not, however, sue for infringement concerning Geneva's capsule ANDA, thus the process foregoes unhindered and the ANDA was approved in March 1998, after which Abbott tries to amend its complaint to also include the capsule formula.

Zenith filed an ANDA in June 1994 for a terazosin hydrochloride, under a paragraph IV certification with respect to Abbott's Hytrin patents. Abbott was issued patents for forms of the terazosin compound in May 1995 (pat. No. 5,412,095) and another in April 1996 (pat. no. 5,504,207). This required Zenith to amend it's ANDA, in regards to the new patents, which they did not, hoping to avoid the 30 month stay of approval and the 180 day delay of approval based on Geneva's ANDAS that were filed earlier.

Zenith chose to sue Abbott instead, claiming that Abbott listed the '207 and '095 patents knowing that they did not cover Hytrin, and demanded a delisting. Abbott countersued for infringement.

The Settlement Agreements

Abbott and Zenith entered an agreement on March 31, 1998. In the "Zenith agreement", Zenith dropped their delisting demands and acknowledged the validity of Abbott's terazosin hydrochloride patents. They thereby admitted that any terazosin hydrochloride compound they released on the market would be in violation of Abbott's patents, and agreed not to market any pharmaceutical compound containing terazosin hydrochloride until someone else marketed a generic compound or until the '532 patent expired. The agreement also stated that Zenith was to refrain from transferring any of their rights under the ANDA provisions, and not to aid any other person trying to invalidate Abbott's patents claiming Terazosin HCl.

Abbott in their turn, dropped their countersuit and agreed to pay Zenith $3 million directly, then another $3 million after

3 months and $6 million every 3 months until March 1, 2000 or until the contract terminated by its own terms. If another generic manufacturer received FDA approval and was granted a 180-day exclusivity period, the payments would be halved until the period ended.

Abbott and Geneva entered their agreement in April 1998, where in Geneva consented not to sell any product containing any form of terazosin hydrochloride, until the ‘532 patent expired, someone else introduced a generic drug or until they obtained a final court judgment (exhausted possibilities of appeal) that the tablets did not infringe the ‘207 patent or the patent found invalid. Geneva also agreed to refrain from transferring or selling its rights under the ANDA provisions, and to oppose any subsequent applicants attempt to seek approval of its application.

In return, Abbott paid Geneva $4.5 million each month until someone else brought a generic product, or until Abbott won its infringement claim in district court. If Geneva won in district court, the money would go into escrow pending the appeal, and be rewarded to the party who prevailed in the appeal case. A clause gave Abbott the right to terminate its payments after February 8 2000, and if they chose to exercise this right, they would drop any infringement case based on the ‘207 patent, in favor of Geneva.

The district court handed down its decision in the infringement case on September 1, 1998, where the court held the ‘207 patent invalid, due to that the form of Terazosin HCl had been on sale in the US one year before Abbott applied for the patent. The Federal Circuit affirmed the verdict on July 1, 1999 and petition for certiorari (Supreme Court) was denied on January 10, 2000.

The parties terminated the settlements in August 1999 as a result of a FTC investigation, but class action and individual suits were filed in a joint motion to deem these agreements per se illegal in violation of §1 Sherman Act on February 18, 2000.

In December 2000, an Order was granted for summery judgment by the District Court, concluding the agreements to be per se violations of the Sherman Act. The agreements were characterized as market allocation agreements; allocating the entire US market for terazosin compounded drugs to Abbott, who in their turn shared their monopoly earnings with the cartel members Zenith and Geneva.

Four anticompetitive elements were found in the Geneva agreement:
1) Geneva refrained from marketing its terazosin capsule until the termination of the agreement, 2) not to market the terazosin tablet until agreement termination, 3) not to transfer ANDA rights and 4) aiding Abbott in opposing other ANDAs attempts to market a terazosin drug.

Three anticompetitive elements were found in the Zenith agreement.
1) Zenith agreeing to dismiss the delisting suit, 2) promising not to aid any third party trying to challenge Abbott's patents validity, and 3) not to market a generic terazosin product until the termination of the agreement.

The gist of the agreements was concluded to be to dissuade generic companies from marketing the first non-brand Terazosin on the US market, for an indefinite period.

3.2.2 Court Decision

Circuit Court begins by examining the exclusionary effects that these agreements might have, in light of that it is these exclusionary effects that are the basis for the *per se* ruling of the District Court.

The Judges conclude that an agreement between competitors to allocate territories, with no other objective than reducing competition is a violation of the Sherman Act, and merits a per se illegality. They continue by stating that this is not such a case, since a patent grants its owner a lawful right to exclude others. A patent holder is within his rights when choosing to be the sole supplier or grant exclusive territorial licenses, carving up the US

among its licensees, geographically, or by costumer class.[52] The court realizes that these practices might have an anticompetitive effect, but not amounting to violations of the Sherman Act.

The actual exclusionary effect of the Zenith agreement was narrower than the exclusionary power of the ‘207 patent, since it allowed Zenith to market a generic terazosin drug on the expiration of Abbott’s ‘532 patent in February 2000, or when another generic drug entered the market. Abbott’s ‘207 patent wasn’t to expire until October 2014.

Geneva’s agreement bound Geneva not to market a generic product until the invalidation of the ‘207 patent by a court of last resort, the marketing of another generic or the expiration of the ‘532 patent, thus not exceeding the already existing exclusionary power of the ‘207 patent.

Since the District Court fails to address the existing exclusionary power of Abbott’s patents in their antitrust analysis, their per se judgment of the agreements must be reversed.

Secondly, the plaintiffs argue that since the ’207 patent was declared invalid, Abbott never had any patent rights, and that addressing the exclusionary effect of that patent must be redundant in the anticompetitive analysis. The court rejects this idea, stating that in all reasonableness, an agreement must be judged under the circumstances that were at hand at the time it was entered, only exception is if the patent was obtained through fraud, or of the patentee knew its patent was invalid or not infringed, i.e. good faith is a complete defense to the an antitrust claim. Since none of these circumstances lay at hand, the patent’s exclusionary effect is very relevant in the analysis.

The plaintiff’s final antitrust arguments are based on the existence of payments flowing from the patentee, to the alleged infringer. Due to the asymmetries of patent litigation risk created by

[52] Valley Drug p 23

Hatch-Watchman provisions, the infringer bears no risk if product is not released, but the patentee ultimately risks of having his patent invalidated. Because of this one cannot view economic compensation to the infringer as a per se prohibition. The exclusionary power lies in the patent, retaining that power through litigation is more costly for the parties, and society, than a settlement is. The court also argues that the size of the payments might give reason to suspect the patentees belief in the strength of the patent, but nothing in these settlements at hand gives reason that this is the case. The mere presence of “exit payments” does not alone demonstrate that the agreements were wider in their exclusionary scope, than what is granted by the patent.

To conclude, the court requires more analysis of the agreements, since the agreements at hand do not limit themselves to restrictions on infringing products and exit payments. The district court must analyze if and to what extent the agreements exceed the scope of the patent, one example being the clauses not to sell “any” competing product. The court remanded the case for further proceedings.

3.2.3 Schering-Plough Corporation, Upsher-Smith laboratories, Inc. vs. Federal Trade Commission.

March 8, 2005

Question

Does ”evidence support(s) the conclusion that the Schering-Plough settlements unreasonably restrain trade in violation of Section 1 of the Sherman Antitrust Act /.../”

Two settlements with two potential competitors Upsher-Smith (Upsher) and ESI Lederle Inc. (ESI) are the base for this case.

Background

Schering is a pharmaceutical company that manufactures and markets “K-Dur 20”, a supplementary drug taken with prescription medicines for the treatment of high blood pressure or congestive heart disease. The active ingredient in K-Dur 20, potassium chloride, is unpatentable. The supplements “extended-release coating” is patented – pat. No. 4 863 734, which expired on September 5, 2006. At the time, K-Dur 20 was the supplement with the highest market share.

In 1995, Upsher sought FDA approval for a generic version of the supplement, called Klor Con M20. ESI sought FDA approval to market its own generic supplement, Micro-K 20. Subsequently, Schering sued both companies for patent infringement.

The Settlement Agreements

The settlement with Upsher was reached one day before the patent trial on June 17 1997. Not willing to pay Upsher just to stay off the market, Schering had been looking to license a cholesterol-lowering drug and became interested to license Upsher’s Niacor-SR (Niacor) in a separate deal. Upsher sold Schering the license to market Niacor worldwide, with the exception of North America, an additional with five other licenses, together with the results from Niacors clinical trials. Based on the information, Schering estimated the net value of Niacor to be between $245-265 million. The earliest date of market entry for Klor Con was set as September 1, 2001, and a license deal between the parties was drawn up, entitling Upsher to receive $60 million in initial royalty fees, $10 million in milestone royalty and 10% or 15% royalties on sales.

The settlement with ESI was reached after a lengthy court-supervised mediation, and signed on January 23, 1998. Schering divided the remaining patent life of K-Dur, and allowed Mikro-K 20 to enter the market on January 1, 2004. ESI was also

granted $5 million to settle the case, attributed to legal fees, and another $10 million if ESI received FDA approval by a certain date, which Schering doubted.

The FTC filed a complaint stating that these settlements were illegal restraints on trade, and thus in violation of Section 5 of the FTC Act, 15 U.S.C. § 45, and section 1 of the Sherman Act 15 U.S.C. § 1. The FTC also accused Schering of monopolizing and conspiring to monopolize the potassium chloride market.

Upsher settlement was not a sound economic transaction, according to the FTC, but merely a horizontal market allocation agreement, proved by Schering's post settlement behavior (did not market Niacor, due Niaspan's lacking sales) and their initial overestimation of Niacors value.

The FTC problem with the ESI settlement concerns the validity of the $10 million payment, which was bound to FDA approval of the generic product by a specific date. They also consider the $5 million for legal fees somewhat excessive.

3.2.4 Court Decision

Although it is acknowledged that an agreement to allocate markets is clearly anticompetitive, but "[i]n the context of patent litigation, however, the anticompetitive effect may be no more than the patent's own exclusionary power."[53]

Neither per se-violation nor the rule of reason approach is suited for cases concerning patent cases, because they seek to find the element, which cripples competition. In patent cases, this element is already present; a patent is by nature a monopoly.

Thus we are bound by the eleventh circuits own analysis of how and if a patent litigation agreement violates antitrust law, or is well within the rights afforded to them by patent laws.

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[53] Schering-Plough p 15

1. One needs to examine how exclusionary the patent already is,
2. does the agreement extend that exclusionary effect,
3. and what are the anticompetitive effects of this extension?

A patent shall be presumed valid. According to patent law, a patentee has the right to exclude others from profiting his patented innovation, and every right to license his rights to market the product wholly or partly. A patentee does not risk suffering antitrust liability for excluding others from producing his patented work. Conclusion must be that Schering's valid patent gave them the right to exclude others from marketing infringing products until the patent expired in September 2006.

The contested agreements granted Upsher the possibility to sell an infringing product five years prior to expiration and ESI two years. There was no proof that these competitors would have had this opportunity in absence of these agreements, which give merit to the strength of the patent. Neither is there any proof of vexatious litigation, nor any evidence that the settlement agreement was anything but a mutually profitable transaction, consistent with what the parties have stated. It is the courts finding that "[p]atent owners should not be in a worse situation, by virtue of the patent right, to negotiate and settle surrounding lawsuits."[54]

The court argues further, that since it is clear that Schering is not creating a greater restraint in trade than the rights given to them by their patent rights, one must see if there are any restraining ancillary clauses.

Hatch-Waxman gives generics a possibility to challenge patents without the risk of making infringing sales. What we usually see as damages for infringement, flowing from the infringer to the patent holder, is redistributed under this provision – the risk taken by

[54] Ibid p 34

a future infringer is limited to the costs of litigation, but the patent holder risks to ultimately lose his patent, thus “even a patentee confident in the validity of it patent might pay a potential infringer a substantial sum in settlement.”[55] The conclusion of the court is that negotiation of the entry date of the generic, and an ancillary transaction for licensing other products from the generic cannot render the settlement illegal from an antitrust point of view.

3.3 The Second Circuit

The Second Circuit adopts and enhances the standard set by the Eleventh Circuit Court, but realizing the conflict between the rule of law (court decision) and policy aims, suggesting in the Ciprofloxacin verdict for the petitioners to re-petition for hearing in banc.

3.3.1 In Re: Tamoxifen Citrate Antitrust Litigation

August 10 2006

Question

Is a settlement agreement that is entered upon after the invalidation of a patent in a District Court, but while the case was pending in an appeal, to be considered a violation of Section 1 Sherman Act?

Background

The plaintiffs claim that Astra Zeneca (Zeneca) and Barr Laboratories Inc. (Barr) conspired to monopolize the market for Tamoxifen by entering a settlement agreement in 1993. Tamoxifen being the most prescribed cancer drug in the world. The patent for Tamoxifen was obtained in August 1985, four months later an ANDA was filed by Barr to market a generic, the application was amended in 1987 to include a paragraph IV certification. Zeneca timely responded with a lawsuit, suing both Barr and their supplier Heumann Pharma GmbH

[55] Valley drug p 13

& Co (Heumann). In April 1992 the district court declared the patent invalid, due to “crucial information” that had been withheld in the patent application.

Zeneca appealed to the Federal Circuit, but the parties settled while the appeal was pending in 1993. In 1994 Novapharm Ltd. challenged the validity of the patent by filing an ANDA with paragraph IV certification, followed by Mylan Pharmaceuticals Inc. and Pharmachemie B.V. in 1996. In each case the validity was upheld.

The settlement

In the settlement agreement Barr agreed to change the paragraph IV certification to a paragraph III certification (thus agreeing not to market a generic version of Tamoxifen until patent expired in 2002) in exchange for $21 million and a non-exclusive license to sell a Zeneca made version of the drug under Barr’s label in the US. Zeneca also agreed to pay Heumann $9.5 million up front and $35,9 million over a period of 10 years.

Furthermore it was agreed that if the patent was subsequently challenged by another generic company and declared invalid in a final and un-appealable ruling, Barr retained the right to revert to a paragraph IV certification, putting Barr in the same position as they would have been in if they had won the appeal instead of settling.

As a part of the settlement Barr had to recognize the validity of the Tamoxifen patent, so the parties filed a “Joint motion to dismiss the Appeal as Moot and to Vacate the Judgment Below”. The motion was granted and the invalidation of the Tamoxifen patent was revoked.

3.3.2 Court Decision

The Plaintiffs Antitrust claims

1. The fact that the *patent was held invalid* in Tamoxifen I, and that the settlement was entered into after that ruling supports the plaintiff's allegations that the defendants conduct was in violation of antitrust laws. The District Court should have treated the patent as "presumptively invalid." [56]

The court cites, amongst others, the Eleventh Circuit in Schering-Plough and agrees that settlements are to be favored over litigation. The court also feared that a severe restriction on patent settlements would increase uncertainty regarding patent rights and therefore decrease innovation.

Then they address the plaintiff's complaint about the validity of the patent by stating that even in the appeal at hand, the Federal Circuit would have reviewed the lesser court's findings instead of presuming validity, or in this case invalidity. In any case, the court states, one is bound to judge the reasonableness of agreements at the time they were entered into. The court also points out the fact that subsequent challengers did not manage to render the patent invalid and although not supporting their ruling on that fact it is a reminder of the unpredictability of such proceedings, they say. The court argues that as long as the underlying litigation is not a sham, the settlement cannot be deemed as violate anti-trust law.

They do not they give the timing of the settlement much consideration, either. There are no limitations in settling a case pending appeal, to eliminate risk of losing. The fact that Zeneca initially litigated should not be held against them, nor seen as a lack of confidence in the validity of the patent, but as proof of the contrary- they hade sufficient confidence in their patent to litigate in the district court.

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[56] In Re: Tamoxifen p 14

2. Excessive 'Reverse Payments'

Reverse payments are an expected product of the Hatch-Waxman Act, since the risks are reversed than in a typical patent infringement case, where the patent holder sues the infringer for it's loss of profits due to the infringement.

A successful patent holder receives not only the right to assert his patent, but also treble damages, but an infringer loses not only the opportunity to do business but also all his initial investments, and pay damages on top of that.

So in the typical case, the flow of money in a settlement would go from the infringer to the patent holder, to avoid losing litigation. Under Hatch-Waxman the generic filing an ANDA with a paragraph IV certification stands almost nothing to lose (save litigation costs) and all the profits of being the first exclusive generic on the market to gain.

The pioneer company has on the other hand, no more to gain than what they already have, a legal monopoly to sell a product covered by a valid patent, but everything to lose in litigation. Merely the fact that it is logical for the patent holder to fend off potential infringers, does not mean that the payment cannot be anticompetitive, argues the court.

But it makes economic sense for a patent holder to pay a portion of the stakes he stands to lose if he loses his monopoly, and it also makes "*obvious economic*"[57] sense for the generic to accept such a payment, argues the court. And even though paying a large sum might indicate the patent holder's weak confidence in the validity of a patent, it would be less than wise to deem a patent invalid based on lack that of confidence. Thus it cannot be said that it is "bad faith" to assert and defend a patent that one privately doubts would be upheld in a suit nor to settle the suit. The court argues that no matter the degree of certainty a patent holder might have, there

[57]In Re: Tamoxifen p 19

will always be a risk of losing, and a willingness to settle can't be discounted to avoid that risk.

In this case, settlement was attractive to Zeneca once they had lost in the District Court, but not necessarily meaning lack of confidence in the patent. The court takes no issue in the fact that the settlement was entered into after a court had ruled against the patent validity, since Zeneca "had displayed sufficient confidence in its patent" by taking the case to trial in the first instance.

The court comments the excessiveness of the payment (plaintiffs argue that Barr received more than they would expect to gain if allowed to enter the market) by stating that if the amount paid had been limited to what objectively had been expected, or to a maximum set by a rule, the level of competition would not be any different. The exclusionary effect and anti-competiveness is not enhanced or reduced by the amount paid by the pioneer company, the Court argues.

They strengthen their argument by adding that even though there might be an obvious risk that weak patents will survive through these payments, nothing is to prevent new generics to challenge the validity, and it is not economically realistic that the patent holder will be able to fend off all challengers with payments. The surplus gained from the monopoly will run out, they argue, and finally a court will declare the patent invalid.

Since "well established principles of law"[58] prevents the court from banning all settlements of Hatch-Waxman infringement actions, and the damage to competition is very much already present in patent cases, the court can only assess whether the terms of the settlement increases the scope of that monopoly.

3. The terms of the Settlement

There are no restrictions in the settlement restraining Barr from launching non-infringing products, as the per-se ban in Cardizem

[58]Ibid p 14 *"courts are bound to encourage"* the settlement of litigation.

prohibits. Zeneca's patent for Tamoxifen is a compound patent, which renders all versions as infringing products.

The settlement also ended the litigation between Barr and Zeneca, immediately opening the field for a potential challenger of the patent.

Furthermore Barr was allowed to sell a licensed product, which leaves the market more competitive, argues the court realizing the limitations to this type of competition (lowering the price with 5%), than if Zeneca had prevailed the appeal.

The court affirms the judgment of the District court and concludes that the settlement agreement did not exceed the exclusionary effect of the patent and did not restrain trade in violation of the Sherman Act.

Dissident opinion

One dissident Circuit judge expresses his opinion in great lengths, criticizing the majority decision of from a public interest point of view. Among his points are that one must also consider the public interest when deciding whether a worthless patent deserves the same level of protection as a patent with great social value. He continues to point out that in this particular case the patent had already been "shown to be vulnerable to attack" and in his view the generic is merely paid to stay off the market, and therefore the public benefit is hard to see.

He continues to address the relativity in risk differentiation under the Hatch-Waxman provisions. First a generic under litigation has a legal stay of 30 months prior to market introduction, and then when and if winning the litigation, a180 day exclusivity. On the other hand, the public gain can be "enormous" claims the dissident, since any generic can enter the market after the 180 exclusivity period, providing the market with immense competition.

The 30-month stay also provides the patentee an incentive to pay the generic more than he would expect if allowed

market entry, because he would be protected against competition for 30 months after the first lawsuit is terminated.

In assessing the reasonableness of an agreement one must consider all the circumstances the dissident follows. “The strength of the patent must be central to any antitrust analysis involving a patent.”[59] Thus in assessing the anti competitiveness of a Hatch-Waxman settlement one needs to start with looking “at the strength of the patent as it appeared” at the time of settlement. Secondarily on the amount transferred between parties, how much the generic expected to gain during the initial 180 days, and finally ancillary anticompetitive provisions.

The dissident judge “expects” that Barr would have prevailed in the appeal, and this would have stopped the subsequent litigations that upheld the patent validity, and therefore it is unfair to use these subsequent litigations as any kind of proof of validity.

3.3.3 In Re: Ciprofloxacin Hydrochloride Antitrust Litigation

29 April 2010

Question

In this third review of the settlement agreement between Bayer and Barr, the concern is whether the agreement is in violation of Section 1 of the Sherman Act, due to the existence of ”reverse exclusionary payments”.

Background

Bayer owns patent for active ingredient in Ciprofloxacin (Cipro), the world’s most prescribed antibiotic, US Patent 4,470,444. Patent was issued in June 1987 and was to expire in December 2003 (additional

[59] In re: Tamoxifen p 38

pediatric exclusivity until June 2004). In 1991 Barr planned to market a generic form of Cipro, and filed a paragraph IV certification under the Hatch-Waxman provisions. Bayer sued timely within 45 days, after which Barr entered into an agreement with other potential competitors to Bayer, to share and bear costs and benefits of the litigation. 2 weeks before the case went to trial, the parties settled in January 1997.

The Settlement

In the settlement Barr agreed to refrain from marketing any generic form of Cipro and acknowledging the ‘444 patents validity. In return Barr was to receive an up front payment of $49,1 million, quarterly payments of between $12.5 million and $17.125 million for the duration of the patent life, save the last two quarters when the generic manufacturers where guaranteed licenses to sell brand name Cipro at reduced rates.

Bayer reserved an option to provide Barr with a license to resell Cipro at a 70% royalty rate, instead of quarterly payments, but never realized that option. Bayer also reserved their right to claim their 180-day exclusivity period, if the ‘444 patent was to be declared invalid by another generic company. In total $398,1 million was paid by Bayer, and though four generic manufacturers tried to challenge the validity of the ‘444 patent in court, no one succeeded.

In 2000, a number of plaintiffs and numerous claims against Bayer was consolidated into one case, the complaint being that the settlement agreement exceeded the scope of the ‘444 patent, and that Barr crippled further competition by keeping the 180 day exclusivity period. The plaintiffs asserted that without these agreements Barr either would have entered the market pending the resolution of the litigation, would have won the litigation case and entered the market, or been granted a license by Bayer to market a generic version of Cipro to avoid litigating the validity of the ‘444 patent.

District court found that the core question was whether the adverse effects on competition brought on by these agreements where outside the natural scope of the '444 patent. They found that the agreements did *not* exceed the exclusionary power of the patent, nor that the parties obstructed future challengers of the patent. The court also stated a patent must be presumed valid. "The fact that Bayer paid what in absolute numbers is a handsome sum to Barr to settle its lawsuit does not necessarily reflect a lack of confidence in the '444 Patent, but rather the economic realities of what was at risk."[60] Neither is it the parties' role to look after the public's interest in lowering the prices when settling out of court. The Federal Circuit granted appeal.

3.3.4 Court decision

By referring to their ruling in *In re: Tamoxifen Citrate Patent Litigation* (Tamoxifen), where the conclusion is that a patent holder is within their rights to protect their monopoly over a patented product, "[u]nless and until the patent is shown to have been procured by fraud, or a suit for its enforcement is shown to be objectively baseless, there is no injury to the market cognizable under existing antitrust law, as long as competition is restrained only within the scope of the patent."[61]

Since plaintiffs do not argue that the lawsuit was vexatious, nor that the patent was wrongfully obtained the court is left with one aspect to investigate: whether the settlements where the generic firm agrees to deter from entering the market in exchange for money falls within the scope of the patent holder's immaterial property rights, or if they are a case of illegal market sharing. But as we've seen in Tamoxifen, a generic version of a compound patented drug (such as the '444 patent and Cipro) is an instantaneous

[60] In re: Ciprofloxasin p 11
[61] In re: Ciprofloxasin p 12

infringement of the patent. When Barr agreed to abstain from manufacturing and marketing a generic version of Cipro, they only abstained from a conduct that would infringe Bayer's immaterial rights under patent law.

Furthermore the plaintiffs claim that the agreements entitled Barr to manipulate it's 180 day exclusivity period, and the generic companies agreed not to file future ANDA-IV certifications relating to Cipro – where conducts that should be viewed as ancillary restraints outside the scope of the patent.

The court acknowledges that manipulating the exclusivity period might be a prohibited conduct, but that although Barr was entitled by the agreement to reinstate its ANDA-IV if the '444 patent was successfully challenged by a third party, this reinstatement would not have granted Barr a 180 day exclusivity period based on the legal scheme at the time. In short – Barr had given up their right to the exclusivity when they stopped challenging the patent.

The court simply states that since the '444 patent was a compound patent; there could be no future ANDA-IV certifications without infringing the patent, thus also falling within the exclusionary scope of the patent.

The court finally identifies some problematic points of their ruling in Tamoxifen, one of the greatest pointed out by the United States:

"This Court's Tamoxifen standard inappropriately permits patent holders to contract their way out of the statutorily imposed risk that patent litigation could lead to invalidation of the patent while claiming antitrust immunity for that private contract… [T]his standard effectively bars considering whether the agreement might violate the antitrust laws, and so offers no protection to the public interest in eliminating undeserved patents." One of the objectives of the Hatch-Waxman Act was to bring more low cost generics to the market, something that is hard to do when bound to their decision under

Tamoxifen.

The court concludes that as long as Tamoxifen is “controlling law” they must rule in accordance, but suggests to the plaintiffs and appellants to repetition for hearing in banc, due to developments after Tamoxifen, where an increase could be seen in settlement agreements with “reverse payments, critique received from the authors of the Hatch-Waxman Act and that the court actually based their ruling on a mischaracterization of the act considering the 180-day exclusivity period as an incentive to challenge weak patents.

3.4 Summary of Caselaw

In Cardizem, the generic agreed not to market *any* generic product until a final court decision or a license agreement was signed (with the Andrx or another generic) in exchange for roughly $90 million. The court found that this agreement exceeded the exclusionary scope of the patent, since it prohibited the marketing of *non-infringing* versions of the patented drug, and deemed the deal as a per se violation of the Sherman Act.

Valley Drug covered two settlements with two generics Zenith and Geneva. In the first one, Zenith acknowledged the validity of all patents, so any generic version would naturally infringe the patents. They promised not to market their drug until another generic entered or patent expired, in exchange for $6 million quarterly for 2 years. In the second settlement, Geneva agreed not to sell any product containing Terazosin HCl until paten expiration or final court judgment freeing from infringement or finding patent invalid. Geneva received $4.5 million/month until another generic entered the market or if they won the infringement case concerning the ‘207 patent, which was found invalid by the district court.

The court found, that in the cases of Zenith and Geneva, the settlements exclusionary powers were actually narrower than the effect of the ‘207 patent – it allowed the parties to market

their products earlier, at the expiration of the ‘532 patent in 2000, and not in 2014, when the ‘207 patent was to expire.

The court refrains from a per se analysis, because the district court has failed to include the exclusionary scope of the patents in their analysis. The court states that they cannot take the later invalidation of the ‘207 patent into consideration, since an agreement must be judged under the circumstances that lay at hand at the time when it is entered.

In Schering- Plough, the Eleventh Circuit Court finds that neither a per se condemnation, nor a rule of reason analysis is appropriate in analyzing the settlements at hand. According to the court, these tools seek to find the crippling effect on competition, something that is already evident in these cases; a patent cripples competition and creates a monopoly.

One must instead look into the exclusionary effect that is inherent in the patent, and whether that effect is exceeded in the settlement, and if so, what are the anticompetitive effects of this excess? In this case, where Schering settled with two parties, without having a patentable active ingredient and paying high royalty fees for license agreements, the court still found the settlements to be within the exclusionary scope of the patents. A patent must be presumed valid, and thus capable of excluding all others from the use of a patented product – one cannot put a patentee in a worse position when settling out of court, merely because they own a patent, they argue.

In Tamoxifen, a patent was declared invalid, and while pending appeal, the parties settled, and vacated the invalidation. The generic was paid $21 million, and licensed to sell brand name made drug under their label, changing their paragraph IV certification to a non challenging paragraph III certification. In response to the timing of the settlement, the court reasons as in Schering-Plough, the timing is irrelevant, the parties must be able to settle in any stage of the litigation. Excessive payments aren’t seen as an issue either –

the amount does not change the exclusionary effect of a patent, or the level of competition in the aftermath of a settlement. The generic here was not prohibited to sell non-infringing products, and the litigation opened up for future challengers.

The dissident opinion raised the question of public gain, as lacking in the courts argument. Between the potential risk of the patentee and the potential gain of the generic, there is a massive *public gain* to consider, argues the dissident judge. This gain was one of the reasons for passing the Hatch-Waxman Act.

In Cipro, one of the most recent judgments, the court continues its course, claiming that as long as the patent is not procured by fraud, and the base for litigation is not unfounded, no harm is done to the market as long as competition is limited within the scope of the patent. The court finishes with stating that although they must rule according to Tamoxifen, they invite the plaintiffs to re-petition for hearing in banc (full court) due to developments after Tamoxifen.

Voices have been raised by legislators about the miss-use of Hatch-Waxman provisions, that where thought to be promoting and facilitating generic market entry, and now increasingly used for monopoly bounty sharing.

3.5 Analysis of Caselaw

Since the settlement cases do not discuss the patent validity issues, it is not a difficult task to conclude what kind of behavior is permissible. The courts repeat their chant – patents are presumed valid.

Considering that patent validity is not an issue, patent holders are seen within their rights to exclude all others from using their protected product in any commercial way. As long as the patentees stay within the “exclusionary power of the patent” they can transfer any value to a potential competitor and stop them from entering the market, as long as the parties can show that the

litigation behind the settlement was not “objectively baseless” or the patent fraudulently procured. The exclusionary effect is dependent on what kind of patent we are dealing with, where the compound patent is the strongest one, making a non-infringing alternative impossible. Other patents are easier to invent around, or reformulate.

Something that has been given an uncontested and essential role in the decisions is the patent validity assumption. Many scholars,[62] the DOJ[63] and FTC[64] have complained that patent validity presumption is merely a procedural tool for courts. The only meaning of the assumption is that in a court of law the proof of burden lies with the party who contests validity, not that all patents are valid. Like all legal presumptions, it is a legal device, not substantive law.

Another aspect, which follows the presumption of validity, is the idea of the exclusionary power of a patent. A patents exclusionary power must be linked to the validity of the patent. A broad patent, or an invalid patent has in fact no exclusionary power. In the American case law, a worthless and invalid patent is awarded the same rights as a useful and valid patent. The objective of the Hatch-Waxman Act was not only facilitate market entry for generics, but doing so through *challenging* weak patents. Court rulings in these cases render weak patents effectively unchallenged. On the other hand, the view that patents are probabilistic also gives rise to issues. This creates uncertainty, giving the patentee lesser protection, a weaker right, something that in the end might cripple innovation.

The courts also argue that in some cases a settlement agreement that divides the remaining patent life between generic and patent holder or in a license situation, leaves the market more competitive than absent an agreement. For example in Tamoxifen prices were lowered with 5% after the agreement. This also gives rise to the question of patent validity. The only case where this can

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[62] American Antitrust Institute Amicus Brief
[63] DOJ Amicus Brief p 19
[64] FTC Amicus Brief p 13

be seen as an increase in competition is if the patent would have been infringed or upheld as valid. In all other cases, competition is worse off.

All courts prefer settlement to litigation, not the least for the public costs it saves. There is no doubt that patent litigation is a costly affair, but is it more expensive compared to the long term costs of having monopoly prices for unchallenged patents? In Europe these costs are often born by the governments through the scope of Socialized medicine plans. In the US, as stated above, 25% of the prescription drug users are senior citizens, many benefiting from Medicare subsidizing, a cost also born by the American government. Although banning settlements in the setting of patent litigation is not the answer, since settlements are such a big part of our legal system, and due to issues of legal certainty and fairness, it is difficult to exempt whole sector from rules of law.

The courts also consider ending litigation as pro-competitive, in the sense that it leaves the field open to new challengers, and in Tamoxifen the court simply states that it is unrealistic that a patent holder can effectively delay invalidation of his weak patent by paying generics to stay off the market. In the end, they will run out of money is the gist of their argument, not taking into consideration the 30-month stay of FDA approval that is put on any ANDA concerning the patent, effectively delaying market entry for all challengers. Depending on when the patent is to expire, the nature of the settlement, this can be an effective way of estopping other generics from entering the market before expiration.

For a better understanding and better overview of what has been accounted for in this thesis, one needs to not only look at the objectives of Antitrust and Competition law, in the US and in Europe but also the reasons for policy. Antitrust and Competition law both stem from the same ground, but have developed differently, not only due to differences in legal tradition, but also in the differences

one can find in the political climate and the creation of policy. Law, as we know, is merely a reflection of policy.

4 Legal economy

Competition and antitrust law are tools that the legislator uses to create a balance on the market, as explained above in the second chapter. *What* is in need of protection and also *how* to protect this subject matter has differed over time, and is based on economic theories. In the years following the Sherman Act, different economic schools emerged and modeled economic theories on both sides of the Atlantic.

The Harvard School theory, mainly developed in the 1930s-1950s at Harvard University, views conduct as a result of a structure. The theory is that conduct gives rise to performance. The Harvard school sought to establish that certain types of structures lead to certain types of conduct that will result in economic performance.[65] This is the Structure -> Conduct -> Performance paradigm (S-C-P-paradigm). In particular, highly concentrated industries, will lead to poor economic performance.

This theory envisaged high entry barriers resulting in few actors leading to oligopoly prices, even in industries with low levels of concentration. The theory together with the American fear of big business (as discussed in chapter 2), lead to an extremely interventionist application of antitrust provisions in the 1950's and 1960's.

The Chicago school criticized this predominantly empirical idea, with a more theoretical approach.[66] These economists believed that the only goal of competition law should be the pursuit of *allocative efficiency*, without carrying any special torch for the protection of small business. As long as efficiency is achieved, who the winner is, is of little importance for the Chicagoans. A great trust is put to the self-regulating capabilities of the market, achieving

[65] The Antitrust Enterprise, Hovenkamp 2005 p 35
[66] The Elgar Companion to the Chicago School of Economics, Emmett 2010 p 10

efficiency with no, or minimum interference. A prerequisite for the Chicago-model is that actors are profit-maximizers; constantly making decisions that increase profit. (All other companies would fall, because the profit maximizing companies would outgrow them, and take their market shares.)

Competition must be understood as the maximizing of consumer welfare, that is, to increase the wealth as much as possible.[67] Consumer welfare is at the greatest when nations economic resources are allocated so that the consumers can satisfy their wants as much as is allowed under current technological possibilities. Antitrust promotes material prosperity, but has no preference or prejudice in how that prosperity is divided; consumer welfare has nothing to do with deciding who should be rich or poor.

The real task of antitrust laws is to improve allocative efficiency (available productive forces and materials) without impairing productive efficiency (co-ordination of production to produce greatest results) too greatly.

The Chicago school has received its share of critique but also left a huge legacy in antitrust reasoning, efficiency is still a central concern. One point overlooked by Chicagoans is strategic conduct of firms. A conduct that cannot be seen as purely profit maximizing, can be adopted to deter and distort competition.

In Europe, although not just an economic theory, Ordoliberalism has had a great impact on policy. Ordoliberalism is a multidisciplinary philosophy, claiming that the protection of competition has a value on its own merits.[68] As a response to the political situation in Nazi Germany, the scholars of Freiburg University claimed that competition is necessary for economic well being, which gives rise to economic freedom, which is essential for political freedom. The Ordoliberal goal is the protection of *competitors*, small and medium sized companies, regardless the

[67] EC Competition Law, Sufrin and Jones 2011 p 26
[68] Ibid. p 35

effects on efficiency. This view has largely influenced the application and enforcement of articles 101 and 102 TFEU.

In 2000 a shift in rhetoric could be heard from the European Commission – consumer welfare was repeatedly explained as the goal of competition. Neelie Kroes, then Commissioner in charge of Competition affaires, asserted the idea that European competition aims were the efficient allocation of resources for increasing consumer welfare.[69]

The General Court of the European Union (ex. CFI) also emphasized this ambition in two decisions, Österreichische Postsparkasse[70] and Glaxosmithklein,[71] stating in the latter that "the objective of the Community competition rules is to prevent undertakings /…/ from reducing the welfare of the final consumer of the products in question." This is a different kind of consumer welfare than what is meant by the Chicagoans. In the European Community, the end consumer is the protected subject matter of law, which is interesting in prescription drug cases, since the end user/consumer is often not the same person as the decision maker/purchaser, or the one who picks up the bill. The user is the patient; the decision maker is a doctor, but also national governments deciding which medicines to subsidize in their role as buyers.

4.1 Patent Settlement Agreements and legal economics

As the court stated in Tamoxifen, the total profits in competition case will be lower than the profits gained by a monopolist. This is simple economics, shown with a graph[72] below.

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[69] EC Competition Law, Jones and Sufrin p 46
[70] T-213/01 Österreichische Postsparkasse AG and Bank für Arbeit und Wirtschaft AG v Commission of the European Communities
[71] T-168/01 GlaxoSmithKline Services Unlimited. v. Commission of the European Communities
[72] Prepared statement of the FTC p 11

As stated in the previous section, the end consumer is not always the bearer of the costs for these pharmaceuticals. In the year 2008 in the US, the Federal government accounted for over 30% of the $235 billion spent on prescription drugs.[74] In Europe, the market for prescription and non-prescription drugs where ¬214 billion.[75]

With this economic reasoning in mind, it is hard to put a price tag on the value of innovation. If the right to settle would be limited, or patent rights devalued, the effects on research and ultimately health improvement could be disastrous if this would lead to less innovation.

In the 73% of the patents in litigation cases in the FTC study and 62% in the Sectorial Inquiry that lead to a final judgment where in fact invalidated or found challengers as non-infringing. The mere figures should not indicate that one should presume that patents are invalid, but as proof of the difficulty of assessing the legality and value of patents and the impact on competition and innovation they can have, when their status is unpredictable. An example of this is found in Tamoxifen, the patent that was initially invalidated in a federal court, but was later upheld as valid when repeatedly challenged by third parties. It would be difficult to restrict the parties abilities right to settle based on the fact that over 50% of patents are declared invalid or non-infringed, but as research by the FTC has shown, 70% of all settlement agreements that where entered into in the scope of their study did not contain a value transfer from the originator to the potential infringer. In Europe 50% of settlements did not restrict the generics market entry. This shows that it is not only possible to enter agreements without value transfers and market limitations, but also that it is quite common.

The world wide economical crisis in the recent years together with higher health costs for the elderly with increasing life

[74] Prepared statement of the FTC p 14
[75] Executive Summary Report

lengths can also be economic factors that shifts focus to cheaper medicines. The question is whether these considerations are short-term? By making patent rights weaker and probabilistic, one creates fewer incentives for new drugs to be researched. In the extreme case, maybe all companies would be waiting for the next big thing to copy, not realizing that nothing new is being developed.

This view is of course a simplification – the bounty that a blockbuster drug renders its owner exceeds R&D costs of that drug; bounty that the company is free to recuperate at monopoly prices during the patent life, if the patent is strong and survives challenges. This bounty is enough incentive for investing to research blockbuster drugs.

The aim of European Competition law is foremost the protection and augmentation of consumer welfare. In the pharmaceutical sector this is to be made possible by giving consumers access to affordable medicines but still keeping the European market attractive for R&D investments.

It is clear that allowing swift market entry of generics augments consumer welfare and in many cases the beneficiaries are not only the end consumers but also the cost bearing governmental bodies. This option might seem extra alluring in these times of international recession. It is also clear that in settlement cases with a value transfer from originator and a limitation to market entry, the economic result is very similar to that of a cartel- more bounty is shared by both parties, than if competition would be allowed. Thus, in economic terms, it would make sense to ban these settlement agreements, claiming that they are not augmenting consumer welfare.

But how would a ban affect innovation? If patent rights would be less valued and restricted in use, what economic consequences would that have? The US courts fear “a chill” on innovation. As we have seen, the majority of settlements contains neither value transfer, nor delays the market entry of the generic.

5 Conclusions

There are many similarities between the legal framework of competition law in the US and in Europe. This is largely due to the common history that the two systems share, but also because of the nature of the subject matter. The prohibited conduct in the Sherman Act and in art. 101 TFEU are similar. The differences are in how to encourage the creation of more wealth, and what to protect, but these views are also converging.

Similarities in section 1 Sherman Act and article 101 TFEU are the views on restraints, banning unreasonable naked restraints on their face, but using pro-competitive aspects with the focus on consumer welfare to make exceptions. Balancing the negative aspects on trade with the positive gains for consumers.

In recent years Europe has been catching up to the American interest in facilitating market entry for generics. In the US the policy for the Hatch-Waxman Act was not only to facilitate generic entry but also to be better equip them when challenging patents.
In Europe the search for affordable medicines created a similar tool for European generic companies, some 20 years later.

The decrease of settlement agreements we see in Europe in 2010 with only 3 agreements of type B.II, was matched in the US in 2004 with 0 agreements of the problematic type. The catalysts that spurred the increase of settlement agreements were court rulings that allowed what before was illegal. In Europe we have several proceedings in court, and the outcome is truly uncertain. We can see that the European Commission adopts the language of the FTC and American courts, using terms like “exclusionary zone” of a patent, but can we interpret that as a convergence in views?

We can see a variety of agreements, ranging from clear violations of competition law to agreements that give no antitrust issues, or with some pro-competitive effects.

An agreement with most harm to competition is one where the patent holder owns a weak patent, pays the opponent a large sum of cash to stay out of the market until that patent expires or later.
An agreement that creates no competition issues is when a risk aversive owner of a strong patent, pays the generic an amount not exceeding expected litigation costs and allowing them market entry before expiration.

As we have seen, the real life examples are often somewhere in between, and the harm in competition is, in my opinion best investigated through a rule of reason analysis, or with our European counterpart in art. 101(3) TFEU.

5.1 Answers to research questions

As we have seen in the American case law, an agreement can be seen as a clear market division and bounty sharing but also be judged as a legal and legitimate way for a patent holder to exercise their right in excluding others. The complexity of these cases makes them ill suited for *per se* condemnation.

To answer the question whether these settlement agreements distort competition, as is meant in article 101 TFEU, one can chose two outlooks. If a patent is presumed valid, then the patent holder is within their right to exclude all others until patent expiration. A transfer of value is of lesser importance, since it does not affect the *amount* of competition on the market; the competition is crippled due to the patent, no matter how much the generic is paid.

Secondly one can view these agreements as distorting competition, because if the patent is invalid or too broad or if the challenger is actually not infringing the patent with his product, then the agreement is merely a way too create a cartel, to the detriment of consumers.

If the ECJ choses to use the same assumption of validity when it comes to patents, it is hard to see how they would reach a different conclusion than their American counterparts; a patentee has the right to exclude all others from the use of their patents, as long as the exclusion fits within the exclusionary scope of the patent.

5.2 Recommendations and final thoughts

The central issue in this thesis, apart from balancing IPR and competition law, is patent validity, something I did not foresee when embarking on this journey. When dealing with the legality of settlement agreements, the courts have refrained in dealing with patent validity, merely stating that the patents are presumed valid.

But in my view, the entire reasoning of the courts is dependent on patent validity. The exclusionary scope of a patent is directly related to its validity. The consumer benefits or restrictions on trade of an agreement cannot be assessed if the patent validity is not settled.

It seems too intrusive to ban the pharmaceutical sector from settling a case out of court, and not a very realistic; therefore I would recommend the creation of a specialized forum for patent litigation and settlements. This specialized court would have the competence to evaluate not only antitrust issues but also patent validity issues. This would increase certainty for litigating parties but also guarantee consumer benefits when they are merited, and patent protection when deserved.

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