Law and Economics of Patent Settlements in the Pharmaceutical Industry

Inaugural - Dissertation

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Vorwort

Diese Dissertation wurde gemäß §8 der Promotionsordnung des Fachbereichs Wirtschaftswissenschaften der Philipps-Universität Marburg vom 8. Juni 2009 erstellt. Sie besteht aus einer Inhaltsübersicht, formalen Inhalten sowie vier eingebrachten Aufsätzen. Insbesondere ist Teil der formalen Inhalte eine inhaltliche Zusammenführung der kumulativen Dissertation in deutscher und englischer Sprache.

Die Dissertation wurde durch Prof. Dr. Wolfgang Kerber, Inhaber der Professur Wirtschaftspolitik an der Philipps-Universität Marburg, als Erstgutachter sowie Prof. Dr. Michael Stephan, Inhaber der Professur Technologie- und Innovationsmanagement an der Philipps-Universität Marburg, als Zweitgutachter, betreut.

Der erste eingebrachte Aufsatz ist im Rahmen eines Sammelbandes veröffentlicht. Der zweite eingebrachte Aufsatz ist in einer früheren Fassung als Diskussionspapier veröffentlicht und erscheint in einem Konferenzsammelband. Der dritte eingebrachte Aufsatz wurde bei einer wirtschaftswissenschaftlichen Zeitschrift eingereicht. Der vierte eingebrachte Aufsatz wird durch die vorliegende Dissertation erstmalig veröffentlicht.

Innerhalb der vorliegenden Dissertation wird auf eine einheitliche Formatierung sowie durchgehende Nummerierung der Seiten verzichtet, um die inkludierten Aufsätze in ihrer jeweiligen Originalversion einzubringen.

Danksagung

Im Besonderen gilt mein Dank auf dem Weg der Erstellung dieser Dissertation meinem Doktorvater Prof. Dr. Wolfgang Kerber, Inhaber der Professur Wirtschaftspolitik an der Philipps-Universität Marburg, der meinen Forschungsprozess in vielfältiger Art und Weise als Betreuer durch wertvolle Hinweise, konstruktive Diskussionen und hilfreichen Austausch begleitet hat.

Ebenfalls möchte ich Prof. Dr. Michael Stephan, Inhaber der Professur Technologie- und Innovationsmanagement der Philipps-Universität Marburg, für die Übernahme des Zweitgutachtens danken.

Danken möchte ich weiterhin Prof. Dr. Rian Beise-Zee, Professor an der Ritsumeikan Asia Pacific University in Beppu, Japan, für die freundliche Unterstützung meines Aufenthalts als RCAPS Visiting Reseach Fellow.

Ich möchte meinen Kolleginnen und Kollegen für den wissenschaftlichen Austausch und die schöne Zeit während der Erstellung dieser Dissertation danken. Mein besonderer Dank gilt Julia Wendel-Hübner, Gabriele Nau, Diane Asobo, Benjamin René Kern, Daniel Möller, Stefan Döpgen, Roman Kersting, Wanja Wellbrock, Christian Rötz, Steffi Lorenz, Enrico Böhme, Matthias Verbeck, Martin Schneider und Peter-Paul Gross.

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im Dezember 2016 Jonas Severin Frank

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Patent Settlements in the Pharmaceutical Industry: An Antitrust Perspective
Autoren: Jonas Severin Frank und Wolfgang Kerber

Erschienen in: Dewenter, Ralf, Haucap, Justus, and Christiane Kehder (Hrsg.): Wettbewerb und Regulierung in Medien, Politik und Märkten, Band 24, Festschrift für Jörn Kruse zum 65. Geburtstag, Baden-Baden: Nomos, S. 385-413 (2013)

Essay 2

Patent Settlements in the Pharmaceutical Industry: What Can We Learn from Economic Analysis?
Autoren: Jonas Severin Frank und Wolfgang Kerber

Frühere Version veröffentlicht in: MAGKS Joint Discussion Paper Series in Economics No. 01-2016 (2016), diese Version erscheint in: Ascola Conference 2015 Konferenzsammelband

Essay 3

Optimal Incentives for Patent Challenges in the Pharmaceutical Industry
Autoren: Enrico Böhme, Jonas Severin Frank und Wolfgang Kerber

Mimeo 2016, eingereicht bei: European Economic Review (EER)

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Patent Settlements in Europe and the Lundbeck Case: A Competition Law and Economics Perspective
Autor: Jonas Severin Frank

Mimeo 2016

Inhaltliche Zusammenfassung der Dissertation in deutscher Sprache

Das Spannungsfeld zwischen Wettbewerb und Innovation ist ein vielfach diskutiertes wirtschaftspolitisches Problem. Dabei steht die Frage im Mittelpunkt wie durch Setzung eines institutionellen Rahmens effiziente Märkte gewährleistet werden können, die sowohl effiziente Preise als auch Innovationen im Sinne der Konsumentenwohlfahrt sicherstellen. Die Wettbewerbspolitik hat insbesondere die Aufgabe einen Rahmen für Vereinbarungen zwischen Unternehmen hinsichtlich dieser Ziele zu setzen. Der Untersuchungsgegenstand dieser Dissertation sind Unternehmensvereinbarungen, die sich auf Patente beziehen und gleichzeitig Wettbewerbsbedenken hinsichtlich der Konsumentenwohlfahrt auslösen. Damit befinden sich diese Vereinbarungen gerade im Spannungsfeld zwischen Wettbewerb und Innovation.

Allgemein wird die Konsumentenwohlfahrt auf der einen Seite durch existierende Produkte und deren Preise und Mengen und auf der anderen Seite durch die Entstehung neuer Produkte und Dienstleistungen beeinflusst. Diese beiden Seiten sind nicht unabhängig voneinander. Aus wirtschaftspolitischer Sicht ist gut verstanden, dass Marktmacht negative Preiseeffekte für Konsumenten hervorruft. Gleichzeitig stellen Marktmacht und Marktmachtgewinne einen notwendigen Anreizmechanismus dar um Innovationen zu ermöglichen. Da der Innovationsprozess mit Kosten, etwa für Forschung und Entwicklung, einhergeht, ist für Unternehmen das Problem der Appropriierbarkeit der resultierenden Renten aus Innovationsprozessen entscheidend. Sofern diese Appropriierbarkeit durch den Innovator nicht ausreichend gewährleistet ist, etwa durch Imitation von Innovationen durch Wettbewerber, besteht das Marktversagensproblem, dass nicht ausreichend in Innovationen investiert wird. Ein Patent ist ein wirtschaftspolitisches Lösungsinstrument für dieses Marktversagensproblem und erteilt dem Innovator eine zeitlich, räumlich und sachlich begrenzte Monopolstellung für die Vermarktung einer Erfindung. In dieser Hinsicht ist das Patent selber ein inhärenter Zielkonflikt, da es auf der einen Seite eine Balance zwischen Innovationsanreizen und auf der anderen Seite dem Problem von negativen Preiseffekten aufgrund der vergebenen Monopolstellung finden muss. Die ökonomische Literatur hat sich ausführlich mit Fragen der Ausgestaltung, etwa der optimalen Länge und Breite, von Patenten befasst.

Vereinbarungen, die Konflikte und Rechtsstreitigkeiten über Patente beenden, werden als Patentvergleiche bezeichnet. Vereinbarungen dieser Art haben eine besondere Bedeutung in der pharmazeutischen Industrie zwischen Originalpräparateherstellern und Generikaherstellern. Auf ihnen liegt das Hauptaugenmerk dieser Dissertation. Der Fokus auf den pharmazeutischen

Sektor wurde gewählt, da Patentvergleiche eine besondere Relevanz in diesem Sektor aufweisen und von Wettbewerbsbehörden und Gerichten untersucht werden. Gleichzeitig sind Diskussionen über dieses Thema in ökonomischen und juristischen Gebieten weit verbreitet. Die Existenz von Patenten sowie die Effekte des Markteintritts von Generika nach dem Auslaufen oder der Annullierung von Patenten hat innerhalb des pharmazeutischen Sektors eine besondere Wichtigkeit. Innovatoren sehen sich hohen Kosten für die Entwicklung sowie Markteinführung von neuen Medikamenten gegenüber. Dies betrifft die Notwendigkeit des Durchlaufens regulatorischer Zulassungsverfahren, langwierige klinische Tests und hohe Misserfolgsquoten. Während diese regulatorischen Erfordernisse, die spezifisch für die pharmazeutische Industrie sind, darauf abzielen die Sicherheit und Effektivität neuer Medikamente sicherzustellen, bedeuten sie auch, dass der Gewährung geistiger Eigentumsrechte eine besonders wichtige Rolle zukommt, um Innovatoren zu ermöglichen ihre erheblichen Investitionen zu refinanzieren. Konsumenten haben ein Interesse daran, dass Innovationsanreize gewahrt bleiben und neue Medikamenten entwickelt werden aber ebenso an einem frühen Markteintritt von Generika, da daraus resultierende Preissenkungen sehr erheblich sind. In diesem Kontext beziehen sich Patentvergleiche auf die Anerkennung von Patentschutz einerseits und auf eine Begrenzung des Markteintritts von Generika andererseits und spielen eine wichtige Rolle in dem Spannungsfeld zwischen Wettbewerb und Innovation im Kartellrecht.

Als Kernproblem kann identifiziert werden, dass ein Patent zwar im Grundsatz im Interesse der Gesellschaft erteilt wird, die Unternehmensvereinbarungen über dieses Patent jedoch Konsumenteninteressen nicht ausreichend berücksichtigen. Dabei ist grundsätzlich zu betonen, dass es dem Patentsystem inhärent ist, dass Patente für nichtig erklärt werden können, etwa aufgrund einer Anfechtung des Patentes durch Wettbewerber. Dieser private Mechanismus der Anfechtung von Patenten, im Interesse der Konsumenten, kann durch Patentvergleiche unterminiert werden. Insbesondere kann dies der Fall sein, wenn sogenannte „reverse payments“ bzw. „reverse value transfers“ in Vergleichen vorliegen, in denen ein „umgekehrter“ Vermögenstransfer von dem Patentinhaber an das Unternehmen stattfindet, das das Patent anfechtet. In der pharmazeutischen Industrie beobachten wir diese Form der Kollusion zwischen Originalpräparateherstellern und Generikaherstellern, die zu einem späteren Markteintritt von Generika führt sowie zu einer Verhinderung der Anfechtung von Patenten durch Generikahersteller. Aus diesem Grund werden diese Vereinbarungen auch als „pay-for-delay“ – Vergleiche bezeichnet. Patentvergleiche mit *reverse payments* sind als allgemeines Problem auch über den pharmazeutischen Sektor hinaus relevant. Die Konsumentenwohlfahrt

wird auf verschiedene Weise durch diese Patentvergleiche beeinflusst, was auch Effizienzeffekte der Vereinbarungen im Sinne der Konsumenten miteinschließt. Es stellt sich die Frage, wie die Patentvergleiche von dem vorliegenden institutionellen Rahmen beeinflusst werden und wie der richtige institutionelle Rahmen für Patentvergleiche aussehen könnte. Diese und andere verknüpfte Probleme erfordern Betrachtungen und Analysen aus einer ökonomischen und rechtlichen Perspektive, welche im Rahmen dieser Dissertation erfolgen sollen.

Die Dissertation adressiert die Forschungsfragen, wie Patentvergleiche bewertet werden sollen, aus einer theoretischen und konzeptionellen Perspektive (Aufsätze 2 und 3) sowie einer interdisziplinären Perspektive (Aufsätze 1 und 4). Der interdisziplinäre Ansatz wendet ökonomische Argumentationen auf komplexe juristische und institutionelle Problemstellungen in der Bewertung von Patentvergleichen an. In dieser Hinsicht trägt die Dissertation sowohl zu der ökonomischen als auch der juristischen Diskussion innerhalb des Forschungsfeldes bei.

Nachfolgend soll eine Übersicht sowie inhaltliche Zusammenführung der zentralen Ziele und Resultate der vier Beiträge, die in der Dissertation enthalten sind, erfolgen.

Aufsatz 1: Frank, Jonas Severin/Kerber, Wolfgang (2013): Patent Settlements in the Pharmaceutical Industry: An Antitrust Perspective, in: Dewenter, Ralf, Haucap, Justus, and Christiane Kehder (Hrsg.): Wettbewerb und Regulierung in Medien, Politik und Märkten, Band 24, Festschrift für Jörn Kruse zum 65. Geburtstag, Baden-Baden: Nomos, S. 385-413 (2013). (Beiträge: Jonas Severin Frank 70%, Wolfgang Kerber 30%)

Der erste Aufsatz der Dissertation hat den Titel „Patent Settlements in the Pharmaceutical Industry: An Antitrust Perspective". Das Ziel des Aufsatzes ist die Analyse von Wettbewerbsproblemen durch Patentvergleiche in den Vereinigten Staaten. Die zentrale Fragestellung des Aufsatzes ist, wie sich die spezifischen Charakteristiken des pharmazeutischen Sektors der USA auf das Problem der Patentvergleiche auswirken, insbesondere hinsichtlich deren Abschluss und der Rolle der Wettbewerbspolitik. Der Artikel konzentriert sich auf die amerikanische Situation, bezieht jedoch die europäische Perspektive mit ein. Um diese Forschungsfrage zu beantworten, wendet der Aufsatz ökonomische Argumentationen auf das Problem der Patentvergleiche an, sowie auf die institutionellen und rechtlichen Rahmenbedingungen. Insbesondere beinhaltet dies eine Analyse der Bedeutung des institutionellen Rahmens des pharmazeutischen Sektors der USA für die ökonomische Analyse von Patentvergleichen und eine Untersuchung von Wettbewerbspolitiken sowie der ökonomischen und juristischen Literatur. Der Hintergrund des Aufsatzes ist die hohe Relevanz

des Problems von Patentvergleichen in den USA und in Europa. Wettbewerbsbehörden und Gerichte haben sich in den USA mit verschiedenen Fällen befasst und teils abweichende Standpunkte vertreten. Außerdem führt die Europäische Kommission Untersuchungen dieser Vereinbarungen durch. Es existieren bisher keine eindeutigen rechtlichen Regeln oder Politiken in beiden Rechtsräumen. Die U.S. Diskussion kann jedoch als weiter entwickelt bezeichnet werden. Sowohl Ökonomen als auch Juristen haben sich mit dem Problem der Patentvergleiche befasst. Des Weiteren ist offensichtlich, dass Regularien des pharmazeutischen Sektors in den USA, bekannt als Hatch-Waxman Act, festlegen wie Generikahersteller in den Markt eintreten können und wie dies mit einer Infragestellung von Patenten und Patentvergleichen zusammenhängt. Ein zentrales Ergebnis des Aufsatzes ist, dass insbesondere Patentvergleiche mit hohen *reverse payments* von Originalpräparateherstellern an Generikahersteller, die gleichzeitig den Markteintritt der Generikahersteller beeinträchtigen, problematisch sind und wettbewerbsrechtliche Maßnahmen auslösen sollten. Mögliche Effizienzvorteile der Vereinbarungen sollten dabei berücksichtigt werden. Ein zweites zentrales Resultat ist, dass der U.S. Hatch-Waxman Act einen starken Einfluss darauf hat, wie Patentvergleiche etabliert werden. Der Aufsatz zeigt, dass das Problem der Patentvergleiche ebenfalls in Europa existiert. Jedoch ist der institutionelle Rahmen deutlich verschieden. In Europa existieren Regulierungen des pharmazeutischen Sektors sowie patentrechtliche Regelungen, die einerseits harmonisiert andererseits national geregelt sind. In den USA beobachten wir ein komplexes institutionelles System, das einerseits darauf ausgelegt ist den Markteintritt von Generika zu beschleunigen, andererseits aber dem Problem gegenübersteht, dass es zu wettbewerbsschädlichen Patentvergleichen führt. Während dieses System Generikaherstellern durch das Mittel einer Patent Infragestellung Anreize ermöglicht schwache Patente zu entfernen, gibt es ebenso Anreize Marktaufteilungen in Rahmen von Patentvergleichen zu betreiben. Das grundlegende Problem, das in diesem Aufsatz adressiert ist, ist, dass Konsumenten an einer Entfernung invalider Patente durch eine Infragestellung von Patenten durch private Akteure interessiert sind, dieser Durchsetzungsmechanismus jedoch ineffektiv ist, wenn in der Folge wettbewerbsschädliche Patentvergleiche beschlossen werden. Ein weiteres Resultat des Aufsatzes ist, dass der gesamte institutionelle Rahmen bestehend aus Regulierungen des pharmazeutischen Sektors, dem Patentrecht sowie Wettbewerbsregeln und ihr Zusammenspiel für die Bewertung von Patentvergleichen relevant sind. Der Artikel weist auf offene Forschungsfragen hinsichtlich des Verständnisses dieses Zusammenspiels von verschiedenen Institutionen hin, um pro- von antikompetitiven Vereinbarungen zu unterscheiden.

Aufsatz 2: Frank, Jonas Severin/Kerber, Wolfgang (2016): Patent Settlements in the Pharmaceutical Industry: What Can We Learn from Economic Analysis?, frühere Version erschienen in: MAGKS Joint Discussion Paper Series in Economics No. 01-2016, diese Version erscheint in: ASCOLA Conference 2015 Konferenzsammelband.
(Beiträge: Jonas Severin Frank 50%, Wolfgang Kerber 50%)

Der zweite Aufsatz der Dissertation hat den Titel „Patent Settlements in the Pharmaceutical Industry: What Can We Learn from Economic Analysis?". Ausgehend von den grundlegenden ökonomischen Resultaten des ersten Aufsatzes, ist das Ziel des zweiten Aufsatzes eine deutlich tiefere Analyse ökonomischer Argumentationen, insbesondere ökonomischer Modelle, für Patentvergleiche und die Herleitung von Schlussfolgerungen für ihre Bewertung. Der Hintergrund des Papiers ist, dass die ökonomische Diskussion bezüglich Patentvergleichen vielfältig ist und auf der einen Seite Argumente existieren, die zu ähnlichen Schlussfolgerungen führen und auf der anderen Seite welche, die zu unterschiedlichen Interpretationen hinsichtlich der Frage führen, wie mit Patentvergleichen umgegangen werden soll. Diese Beobachtung resultiert aus dem Vorhandensein verschiedener Effekte, die in den Analysen berücksichtigt werden sowie verschiedenen Annahmen, die in den ökonomischen Modellen Verwendung finden. Daher hat der Aufsatz die Aufgabe die ökonomische Diskussion bezüglich Patentvergleichen zu strukturieren, existierende ökonomische Modelle über Patentvergleiche zu analysieren sowie gemeinsame wie auch spezifische diesbezügliche Argumente zu identifizieren. Der Aufsatz beinhaltet eine kritische Reflexion darüber, welche Argumentationen unterstützt werden können und was wir von der ökonomischen Analyse lernen können. Der Aufsatz führt eine breite Literaturuntersuchung bezüglich der ökonomischen Diskussion um Patentvergleiche durch und liefert eine strukturierte ökonomische Analyse des Problems. Ferner untersuchen wir die spezifische Verbindung zwischen der Problematik schwacher Patente (*weak* oder *probabilistic patents*) und Patentvergleichen. Da wir aus empirischer Sicht wissen, dass Patente mit einer gewissen Wahrscheinlichkeit für nichtig erklärt werden, besteht aus der Sicht der Konsumenten ein Interesse daran schwache Patente auf ihre Validität zu überprüfen und gegebenenfalls zu entfernen. Der Aufsatz zeigt, dass Patentvergleiche mit dieser Problematik der schwachen Patente und generellen Problemen des Patentsystems eng in Verbindung stehen. Das zentrale Resultat des Aufsatzes ist, dass wir drei Gruppen von Effekten identifizieren, die für die ökonomische Analyse von Patentvergleichen relevant sind: Preiseffekte, Innovationsanreizeffekte und Anreizeffekte schwache Patente infrage zu stellen (Anreize für Nichtigkeitsklagen). Es wird gezeigt, dass diese drei Effekte miteinander zusammenhängen und komplexe Zielkonflikte hervorrufen, die für die integrierte Berücksichtigung von Wettbewerb und Innovation wichtig sind. Zum Beispiel könnte eine

Verhinderung von Kollusion, und damit negativer Preiseffekte aufgrund von Patentvergleichen, bedeuten, dass akzeptiert werden muss, dass weniger Patente überhaupt infrage gestellt werden. Ebenso könnten richtige Innovationsanreize in der Abwägung mit Preiseffekten bedeuten, sehr kritisch gegenüber Patentvergleichen mit einer Verzögerung des Markteintritts von Generika im Vergleich zu einer gerichtlichen Klärung zu sein. Durch die Analyse der unterschiedlichen Modelle identifiziert der Aufsatz Parameter, wie die Höhe der *reverse payments*, die für eine Bewertung des wettbewerbsschädigenden Potentials von Patentvergleichen befürwortet werden können. Gleichzeitig stellen wir fest, dass das Abschließen von Patentvergleichen ein komplexer Verhandlungsprozess ist, in dem unterschiedliche Faktoren den jeweiligen Ausgang beeinflussen können, insbesondere inwiefern eine Vereinbarung wettbewerbsschädlich ist oder nicht. Es gibt ökonomische Argumente bezüglich spezifischer Fälle, in denen Vereinbarungen mit *reverse payments* wolhfahrtssteigernd sein können, sowie Fälle, in denen Vereinbarungen ohne diese Zahlungen wolhfahrtsschädigend sein können. Daher betonen wir, welche Faktoren und Effekte für die Bewertung von Patentvergleichen relevant sind und wie sie miteinander in Verbindung stehen. Neben ökonomischen Modellen für Patentvergleiche wird miteinbezogen, dass die sehr komplexe Bewertung von Patentvergleichen selber Fehlerkosten unterworfen ist, insbesondere wenn alle verschiedenen relevanten Faktoren und Effekte berücksichtigt werden. Dies führt uns zu der Schlussfolgerung, dass wir hinsichtlich Patentvergleichen mit *reverse payments* skeptisch sein sollten, indem wie hier eine Wettbewerbsschädigung vermuten mit sehr limitieren Möglichkeiten ihrer Widerlegung. Unser Papier zeigt wichtige Forschungslücken bezüglich der drei Effekte, die in unserem Papier dargelegt wurden, auf. Für die Bestimmung der besten Kombination von Politiken aus Wettbewerbsrecht und Patentrecht bei der Bewertung von Patentvergleichen weisen wir auf die Wichtigkeit der integrierten Beachtung dieser drei Effekte hin. Wir betonen, wie die spezifische Problematik schwacher Patente mit Patentvergleichen und diesbezüglichen Politiklösungen zusammenhängt.

Aufsatz 3: Böhme Enrico/Frank, Jonas Severin/Kerber, Wolfgang (2016): Optimal Incentives for Patent Challenges in the Pharmaceutical Industry, mimeo, eingereicht bei: European Economic Review (EER).
(Beiträge: Enrico Böhme 40%, Jonas Severin Frank 40%, Wolfgang Kerber 20%)

Der dritte Aufsatz der Dissertation hat den Titel „Optimal Incentives for Patent Challenges in the Pharmaceutical Industry". Das Ziel des Aufsatzes ist es, das Zusammenspiel zwischen Anreizen Patente infrage zu stellen sowie Preiseffekten in Patentvergleichen durch die Einführung eines Politikparameters zu modellieren und eine optimale Politik aus Sicht der

Konsumentenwohlfahrt abzuleiten. Der Hauptbeitrag unseres Papiers zu der Diskussion um Patentvergleichen ist, dass wir in einer neuen Art und Weise Implikationen einer Anreizschaffung für die Infragestellung von Patenten sowie gleichzeitig die Entstehung von Kollusion analysieren. Der Artikel verwendet Erkenntnisse besonders aus dem zweiten Aufsatz, dass diese beiden Effekte, neben anderen, für die Bewertung von Patentvergleichen relevant sind, wobei Zielkonflikte hinsichtlich ihrer Analyse existieren. Wir modifizieren ein gegebenes mikroökonomisches Modell, in dem von einem Originalpräparatehersteller und Halter eines Patentes, das mit einer gewissen Chance für nichtig erklärt wird, und zwei Generikaherstellern, die sequentiell darüber entscheiden das Patent infrage zu stellen und in den Markt einzutreten, ausgegangen wird. Die Infragestellung des Patentes geht mit Kosten einher. Die Parteien können Patentvergleiche eingehen (mit *reverse payments*) oder eine Ausweichoption wählen, das Patent vor Gericht infrage zu stellen. Jedoch müssen diese, im Ausgangsfall, im Einklang mit den Wettbewerbsregeln stehen, was bedeutet, dass der Markteintritt von Generika nur bis zu einem Punkt verzögert werden kann, der dem erwarteten Markteintritt im Zuge eines Gerichtsverfahrens einer Infragestellung entspricht. Wir modellieren das Problem, dass die Gesellschaft auf der einen Seite ein Interesse daran hat, invalide Patente zu entfernen und einen frühen Markteintritt von Generika zu erreichen, und auf der anderen Seite adäquate Anreize für kostenintensive Nichtigkeitsklagen bestehen sollten. Unser Modell für Patentvergleiche nutzt einen Politikparameter, der zusätzliche Zeit für Kollusion spezifiziert, die den Parteien gewährt wird, um korrekte Anreize für das Infragestellen von Patenten zu erreichen. In einem nächsten Schritt maximieren wir die Konsumentenwohlfahrt durch die Spezifizierung des korrekten Politikparameters. Wir zeigen, dass der Zielkonflikt zwischen der Anreizschaffung für Patentnichtigkeitsklagen und den negativen Preiseffekten durch Kollusion existiert. Ebenfalls ermitteln wir den optimalen Politikparameter. Das zentrale Resultat des Aufsatzes ist, dass unser Politikparameter (sofern ungleich Null) unter sehr allgemeinen Bedingungen strikt vorteilhaft für Konsumenten ist und dass der optimale Politikparameter, abhängig von Parameterkonstellationen, positiv oder negativ sein kann. Sofern der Politikparameter positiv ist, bedeutet das, wie sollten Kollusion erlauben, jedoch bedeutet es auch, dass wir *reverse payments* in Patentvergleichen rechtfertigen können. Sofern der Politikparameter negativ ist, bedeutet das, dass selbst der erwartete Markteintritt der Generika ohne Patentvergleich, also mit gerichtlicher Klärung des Patentkonflikts, zu spät ist. Die Konsumentenwohlfahrt kann dadurch erhöht werden, dass ein früherer Markteintritt der Generika gewählt wird, was jedoch aufgrund der bestehenden Ausweichoptionen und Anreize der Parteien nicht ohne weiteres durchsetzbar ist. Ein negativer Politikparameter bedeutet

dennoch, dass alle abgeschlossenen Patentvergleiche, mit und ohne *reverse payments*, wettbewerbswidrig sind. Durch Anwendung von komparativer Statik, und einer teils weiteren Spezifizierung des Modells, können wir zeigen, dass wir mehr Kollusion in Patentvergleichen gewähren sollten, wenn es schwieriger ist Patente infrage zu stellen (beispielsweise durch höhere Markteintrittskosten für Generikahersteller oder intensiveren Wettbewerb). Unsere Modellierung bezieht auf eine innovative Art und Weise, nämlich durch die explizite Verwendung eines Politikparameters, Preiseffekte und Anreizeffekte für die Infragestellung von Patenten bei der Analyse von Patentvergleichen mit ein. Dies erlaubt uns die Untersuchung der Wirkung der Dauer von Kollusion (gesteuert durch unseren Politikparameter) auf die Anreize zur Infragestellung von Patenten und damit die Konsumentenwohlfahrt. Wir sind in der Lage klare Aussagen über optimale Anreize für die Infragestellung von Patenten und die Rolle von Kollusion in Patentvergleichen abzuleiten, die einen wichtigen Beitrag zu der Diskussion in diesem Feld darstellen. Wir diskutieren Limitierungen und Schwierigkeiten das Modell direkt in der Wettbewerbspolitik anzuwenden sowie mögliche Perspektiven für Erweiterungen und zukünftige Forschung.

Aufsatz 4: Frank, Jonas Severin (2016): Patent Settlements in Europe and the Lundbeck Case: A Competition Law and Economics perspective, mimeo.
(Beitrag: Jonas Severin Frank 100%)

Der vierte Aufsatz der Dissertation hat den Titel „Patent Settlements in Europe and the Lundbeck case: A Competition Law and Economics Perspective". Das Ziel des Aufsatzes ist es die europäischen Politiken für Patentvergleiche, insbesondere die Lundbeck Entscheidung der Europäischen Kommission, aus einer wettbewerbsrechtlichen und ökonomischen Perspektive zu analysieren und Empfehlungen zu entwickeln. Es werden sowohl die juristische Perspektive, durch die Analyse von Falldokumenten, offiziellen Leitlinien sowie der juristischen Diskussion, als auch die ökonomische Perspektive durch die Verwendung von vielfältigen Erkenntnissen der ökonomischen Theorie über die Bewertung von Patentvergleichen miteinbezogen. Lundbeck ist einer der wichtigen Fälle über Patentvergleiche mit *reverse payments* in Europa und hat ebenfalls zu einer Entscheidung des Gerichtshofs der Europäischen Union geführt, der die Entscheidung der Europäischen Kommission bestätigt hat. Der Hintergrund des Aufsatzes ist, dass in den letzten Jahren in Europa ein hohes Maß an Untersuchungen von Patentvergleichen beobachtet werden kann. Jedoch finden wir kein klares Bewertungsschema für den Umgang mit diesen Vereinbarungen, sondern eher sich entwickelnde Politiken, die durch die Europäische Kommission sowie Gerichtsentscheidungen ausgestaltet werden. Daher war die Motivation für diesen Aufsatz zu analysieren, ob der Lundbeck Fall richtig entschieden worden ist und was

dies für die breitere Perspektive und Problemfelder von Politiken für Patentvergleiche in Europa bedeutet. Der Artikel baut auf Erkenntnissen auf, die in allen drei vorherigen Aufsätzen gewonnen worden sind, die in dieser Dissertation enthalten sind. Es werden Erkenntnisse hinsichtlich des pharmazeutischen Sektors und des institutionellen Rahmens in den USA sowie der U.S. Wettbewerbspolitik bezüglich Patentvergleichen verwendet (welche der Fokus des ersten Artikels waren), um die Frage zu beantworten, was Europa von den USA lernen kann. Außerdem werden ökonomische Erkenntnisse verwendet, wie mit Patentvergleichen umgegangen werden soll (welche der Fokus der Artikel 2 und 3 waren). Ein zentrales Resultat des Artikels ist, dass die Entscheidung der Europäischen Kommission den Originalpräparatehersteller Lundbeck sowie mehrere Generikahersteller für die Verzögerung des Markteintritts von Generika in Verletzung des Wettbewerbsrechts mit Strafzahlungen zu belegen, befürwortet werden kann. Der komplexe Fall wird auf der Basis von ökonomischen Argumentationen analysiert. Ein weiteres Resultat ist, dass der Lundbeck Fall speziell ist, so dass das Ziehen von Rückschlüssen für andere Fälle oder Fallgruppen begrenzt ist. Um weitere Erkenntnisse zu gewinnen analysiert der Artikel die Europäischen Leitlinien über Technologietransfer-Vereinbarungen, die das Problem der Streitbeilegungsvereinbarungen (Patentvergleiche) explizit miteinbeziehen. Generelle Problemfelder in der Bewertung von Patentvergleichen sowie Beiträge und Limitierungen der Leitlinien werden strukturiert und diskutiert. Der Artikel fragt des Weiteren, was wir von der U.S. Diskussion lernen können und zeigt wichtige institutionelle Unterschiede bezüglich des Patentrechts und der Regulierung des pharmazeutischen Sektors auf, die eine hohe Relevanz für die Bewertung von Patentvergleichen aufweisen. Es wird offensichtlich, dass die Bewertung von Patentvergleichen so komplex ist, dass sie eine Einbeziehung von vielen unterschiedlichen Effekten und Faktoren notwendig macht. Dies gilt auch für die Quantifizierung von *reverse payments* und die Feststellung ihres antikompetitiven Potentials. Der Aufsatz verwendet Argumente aus der ökonomischen Analyse von Fehlerkosten, um eine spezifische Strukturierung der Bewertung von Patentvergleichen zu empfehlen. Die Empfehlung unterscheidet zwischen der Verwendung einer starken Vermutung der Wettbewerbswidrigkeit von Vergleichen mit *reverse payments* sowie einer Freistellung von Vergleichen ohne diese. Der Artikel weist auf Perspektiven für zukünftige Forschung hin, die Erkenntnisse über eine weitergehende Unterscheidung zwischen verschiedenen Fallgruppen liefern könnte, um verfeinerte Bewertungsschemata für Patentvergleiche zu entwickeln.

Die vier Beiträge, die in dieser Dissertation enthalten sind, analysieren die Problematik von Patentvergleichen jeweils aus einer eigenen Perspektive. Wie dargestellt existieren

Anknüpfungspunkte zwischen den einzelnen Aufsätzen. Dies trägt zu einer Beantwortung der Gesamtfragestellung dieser Dissertation bei. Insgesamt lässt sich konstatieren, dass die Bewertung von Patentvergleichen eine ökonomische Analyse ihrer Wirkungen innerhalb des institutionellen Rahmens des pharmazeutischen Sektors notwendig macht. Die Konsumentenwohlfahrt, die das normative Bewertungskriterium ist, wird durch unterschiedliche Effekte in Patentvergleichen beeinflusst, was sowohl ihre Reduzierung, als auch ihre Verbesserung miteinschließt. Dies gilt vor allem, wenn die Vereinbarungen im Zusammenhang der Probleme des Patentsystems gesehen werden. Diese Dissertation weist auf relevante Faktoren für Bewertungsentscheidungen für Patentvergleiche hin und wie sie zu dem institutionellen Rahmen, insbesondere der Wettbewerbspolitik, in Verbindung stehen.

Inhaltliche Zusammenführung der Dissertation in englischer Sprache

Summary of the Doctoral Dissertation

The tradeoff between competition and innovation is a much-discussed problem in economic policy. The central question is how efficient markets can be ensured by setting an institutional framework which guarantees efficient prices and innovation from a consumer welfare perspective. Competition policy, in particular, has the task to set a framework for agreements between firms regarding these goals. The subject matter of this dissertation is to study agreements between firms which relate to patents and at the same time raise competition concerns regarding consumer welfare. For this reason, these agreements are an essential part of the tradeoff between competition and innovation.

Generally, consumer welfare is influenced by existing products and their prices and quantities on one hand, and by the emergence of new products and services on the other hand. These two sides are not independent from each other. From an economic policy perspective, it is well understood that market power results in negative price effects for consumers. At the same time market power and resulting profits ensure an essential incentive mechanism to enable innovation. Since the innovation process goes along with costs, for instance for research and development, firms face the critical problem of the approbiability of resulting rents from innovation processes. In case this approbiability of the innovator is not sufficiently ensured, for instance through imitation of innovation by competitors, the market failure problem exists that there are not sufficient investments in innovation. A patent is an economic policy solution for this market failure problem and grants to the innovator a monopoly right which is temporally, locally and objectively limited for the marketing of an invention. In this regard the patent itself is an inherent tradeoff, because it must find a balance between innovation incentives on one hand and the problem of negative price effects because of the granted monopoly position on the other hand. The economic literature has extensively discussed the question of the optimal design of patent rights, for example their optimal length and breadth.

Agreements which settle or prevent disputes and litigation about a patent's validity are called patent settlements. Agreements of this kind have a particular importance in the pharmaceutical industry between originator and generic firms. They are the main focus of this dissertation. The focus on the pharmaceutical sector has been chosen since settlement agreements are highly relevant in this sector and competition authorities and courts put them under scrutiny. At the same time, we observe prevalent discussions about this topic in the economic and legal fields.

The existence of patents as well as the effects of generic market entry after the expiry or invalidation of a patent is particularly important in the pharmaceutical sector. Innovators face high costs in developing a drug and introducing it to the market. This includes the requirement to go through regulatory proceedings for marketing approval, lengthy clinical trials as well as high failure rates. While these regulations which are specific to the pharmaceutical industry aim at ensuring the safety and efficacy of new drugs, they also mean that granting intellectual property to innovators to recoup their considerable investments is highly important. Consumers have an interest in maintaining innovation incentives and the development of new drugs but also in early generic market entry causing prices to drop significantly. In this context, patent settlement agreements relate to the recognition of patent rights on one hand, and to a restriction of market entry on the other hand, so that they play an important role in the tradeoff between competition and innovation in antitrust.

As core-problem can be identified that, even though patents are generally granted on the basis of society's interests, firms' agreements, relating to these patents, do not sufficiently take consumer interests into account. It shall generally be emphasized that it is inherent to the patent system that patents might be invalidated, e.g. as a result of patent challenges of competitors. This private mechanism to challenge patents, in the interest of consumers, can be undermined by patent settlements. In particular, this can be evident in case "reverse payments" or "reverse value transfers" in settlements exist, where a value transfer from the patent holder to the firm which challenges the patent takes place. In the pharmaceutical industry, we observe this kind of collusion between originators and generics which leads to later generic market entry and to the prevention of generic patent challenges. For that reason, these agreements are also referred to as "pay-for-delay" - settlements. Patent settlements with reverse payments, as a general problem, are relevant beyond the pharmaceutical sector. Consumer welfare is influenced by these patent settlement agreements in many ways, which also includes efficiency effects of the agreements in the interest of consumers. This raises the question how patent settlements are influenced by the institutional framework and how the right institutional framework for patent settlements could look like. These and other interrelated problems require considerations and analyses from an economic and legal perspective which shall be conducted in this dissertation.

The dissertation addresses the research questions how patent settlements should be assessed from a theoretical and conceptual perspective (essays 2 and 3) as well as an interdisciplinary perspective (essays 1 and 4). The interdisciplinary approach applies economic reasoning to complex legal and institutional problems in the assessment of patent settlements. To that

extent, the dissertation contributes both to the economic as well as the legal discussions in the research field.

In the following, an overview and a consolidation shall be provided regarding the central objects and results of the four essays included in the dissertation.

Essay 1: Frank, Jonas Severin/Kerber, Wolfgang (2013): Patent Settlements in the Pharmaceutical Industry: An Antitrust Perspective, in: Dewenter, Ralf, Haucap, Justus, and Christiane Kehder (eds.): Wettbewerb und Regulierung in Medien, Politik und Märkten, Vol. 24, Festschrift für Jörn Kruse zum 65. Geburtstag. Baden-Baden: Nomos, pp. 385-413 (2013) (Contributions: Jonas Severin Frank 50%, Wolfgang Kerber 50%)

The first essay of the dissertation has the title “Patent Settlements in the Pharmaceutical Industry: An Antitrust Perspective”. The objective of the essay is to analyze antitrust problems of patent settlements with focus on the pharmaceutical sector in the United States. The central question which is raised in the essay is how the specific characteristics of the U.S. pharmaceutical sector affect the patent settlement problem, in particular the conclusion of patent settlements, and which role antitrust policies play. The article focuses on the U.S. situation but takes into account also the European perspective. To answer this research question, the essay applies economic reasoning to the patent settlement problem and its institutional and legal framework. In particular, this includes an analysis of the role of the institutional framework of the U.S. pharmaceutical sector for the economic assessment of patent settlements as well as a review of antitrust policies and the economic and legal literature. The background of the essay is the high relevance of the problem of patent settlements in the U.S. and the EU. Antitrust authorities and courts in the U.S. have dealt with various cases with partly deviating standpoints. Also, there is scrutiny of the European Commission towards the agreements. No clear legal rules or policies exist yet in both jurisdictions. The U.S. discussion however is further developed. Both economic and legal scholars have dealt with the patent settlement problem. It is moreover evident that the U.S. pharmaceutical sector regulation, the Hatch-Waxman Act, establishes how generics can enter the market and how this is linked to patent challenges and patent settlements. One central result of the essay is that particularly patent settlements with large so-called “reverse” payments from originators to generics, which at the same time restrict generic entry, are problematic and should elicit antitrust action. Potential efficiency advantages of the agreements should be taken into consideration. A second central result is that the U.S. Hatch-Waxman Act has a strong influence on how settlements are established. The essay shows that the problem of anticompetitive patent settlements does also exist in Europe. However, the institutional framework is clearly different. In Europe, there exist

pharmaceutical sector regulations as well as patent laws which are partly harmonized and partly national. In the U.S., we find a complex institutional system which, on one hand, is designed to foster market entry of generic firms, and, on the other hand, faces the problem that it leads to anticompetitive patent settlements. While this system provides incentives for generic firms to remove invalid patents by means of patent challenges, it also gives incentives to engage in market sharing through patent settlements. The underlying problem, addressed in the essay, is that it is in the best interest of consumers to have invalid patents removed by means of private patent challenges but that this enforcement mechanism is ineffective if anticompetitive patent settlements in the course of such patent challenges are concluded. A further result of the essay is that for patent settlement assessment the entire institutional framework is relevant consisting of pharmaceutical sector regulation, patent law and antitrust rules as well as their interplay. The article points to open research questions regarding the understanding of this interplay of different institutions to disentangle pro- from anticompetitive patent settlements.

Essay 2: Frank, Jonas Severin/Kerber, Wolfgang (2016): Patent Settlements in the Pharmaceutical Industry: What Can We Learn from Economic Analysis?, earlier version published in: MAGKS Joint Discussion Paper Series in Economics No. 01-2016, this version forthcoming in: ASCOLA Conference 2015 Proceedings.
(Contributions: Jonas Severin Frank 50%, Wolfgang Kerber 50%)

The second essay of the dissertation has the title “Patent Settlements in the Pharmaceutical Industry: What Can We Learn from Economic Analysis?”. Starting from the basic economic findings of the first article, the objective of this essay is to analyze much deeper economic reasoning, in particular economic models, on patent settlements and draw conclusions for patent settlement assessment. The background of the paper is that the economic patent settlements debate is diverse and we observe, on one hand, economic arguments leading to rather similar conclusions, and, on the other hand, economic arguments leading to different interpretations regarding the assessment of patent settlements. This is due to differences in effects which are taken into account in the analyses and due to differences in assumptions which are made in economic models. Thus, the essay has the task to structure the economic patent settlement discussion, analyze existing economic patent settlement models and identify common arguments and specific reasoning thereof. The essay also critically reflects which reasoning can be supported and what we can learn from economic analysis. The essay conducts a broad literature review about the economic patent settlement discussion and provides a structured economic analysis of the problem. Further, we examine the specific problem of weak patents (probabilistic patents) and patent settlements. Since from an empirical

perspective we know that patents are found invalid with some probability, consumers have an interest that the validity of weak patents is tested and they are eventually removed. The essay shows that patent settlements relate closely to this weak patent problem and to the more general problem of the patent system. The central result of the essay is that we identify three channels of effects which are relevant in the economic analysis of patent settlements: Price effects, innovation incentives effects and effects on the incentives to challenge weak patents. It is shown that these three effects are intertwined and cause complex tradeoff problems which are important for the integrated consideration of competition and innovation. For example, to prevent collusion and therewith negative price effects in patent settlements might mean to accept that fewer patents are challenged in the first place. Also, to give correct innovation incentives in consideration of price effects might mean being also very critical towards patent settlements with generic entry restrictions in comparison to litigation. In analyzing the different models, the essay identifies parameters, like the size of the reverse payment which can be supported for assessing the anticompetitive potential of patent settlements. At the same time, we find that the conclusion of settlements is a complex bargaining process in which different factors can influence respective outcomes, particularly whether a settlement is anticompetitive or not. There exist economic arguments regarding specific cases in which agreements with reverse payment are welfare-enhancing and cases in which agreements without these payments are welfare-decreasing. Thus, we highlight which factors and effects are relevant in the assessment of patent settlements and how they relate to each other. Besides economic models of patent settlements the essay takes into consideration that the very complex assessment of patent settlements itself might result in error costs, particularly if taking into account all different relevant factors and effects. This leads us to the conclusion that we should be skeptical towards patent settlements with reverse payments by holding them presumptively illegal with limited grounds for rebuttal. Our paper notes important gaps in research regarding the three channels of effects which are laid out in our paper. For determining the best combinations of policies for patent settlement assessment from competition law and patent law we point to the importance of an integrated view of these three channels of effects. We emphasize how the specific problem of weak patents relates to patent settlements and ensuing policy solutions.

Essay 3: Böhme Enrico/Frank, Jonas Severin/Kerber, Wolfgang (2016): Optimal Incentives for Patent Challenges in the Pharmaceutical Industry, mimeo, submitted to the European Economic Review (EER).
(Contributions: Enrico Böhme 40%, Jonas Severin Frank 40%, Wolfgang Kerber 20%)

The third essay of the dissertation has the title “Optimal Incentives for Patent Challenges in the Pharmaceutical Industry”. The objective of the essay is to model the interplay of patent challenging incentive effects and price effects in patent settlements by introducing a policy parameter and to derive an optimal policy for consumer welfare. The main contribution of our paper to the patent settlement discussion is that we analyze, in a new way, consumer welfare implications of incentivizing patent challenges and creation of collusion at the same time. The article uses insights particularly from the second essay that these two effects, amongst others, are relevant for patent settlement assessment while there exist tradeoffs in their analysis. We modify an existing microeconomic model where we have one originator, holding a patent with a chance to be found invalid, and two generics, sequentially deciding on challenging the patent and entering into the market. Challenging the patent is costly. Parties can engage in patent settlements (with reverser payments) or choose an outside option to litigate the patent in court. However, in the benchmark case, they need to comply with antitrust regulation which means that generic entry must not be delayed beyond the expected entry under litigation. We model the problem that, on one hand, society has an interest in removing invalid patents and in early market entry of generics, and, on the other hand, firms need adequate incentives for costly patent challenges. Our settlement model uses a policy parameter specifying additional time for collusion granted to the parties in patent settlement agreements for giving correct incentives to challenge patents. In a next step, we maximize consumer welfare through specifying the correct policy. We show that the tradeoff between incentivizing more patent challenges and the negative price effect from collusion exists. We also find a formulation for the optimal policy parameter. The central result of the essay is that our optimal policy parameter (if unequal to zero) is strictly beneficial for consumers under very general conditions and that the optimal policy parameter can be positive or negative depending on parameter constellations. In case the policy parameter is positive this means we should allow collusion but it also means that our model can give justification for reverse payments in patent settlements. In case the policy parameter is negative, this means that even the expected generic market entry without a patent settlement, so with litigating the patent, is too late. Consumer welfare can be increased by choosing an earlier generic market entry which however is not enforceable because of the existing outside option and incentives of the parties. A negative policy parameter means that all settlements, with and without reverse payments, are anticompetitive. By applying comparative statics, and by partly further specifying the model, we can show that we should grant more collusion for parties in settlements if it is more difficult to challenge patents (e.g. because of higher market entry costs for generic firms or more intense competition). Our modelling includes

in an innovative way, meaning by explicitly using a policy parameter, price effects and challenging incentive effects in the analysis of patent settlements. This allows us to examine the effect which the period of collusion, stipulated by our policy parameter, has on the incentives to challenge patents and on consumer welfare. We can derive clear conclusions about optimal challenging incentives and the role of collusion in patent settlements which are an important contribution to the discussion in the field. We discuss limitations and difficulties in directly applying the results of our model to competition policy and possible perspectives for extensions and future research.

Essay 4: Frank, Jonas Severin (2016): Patent Settlements in Europe and the Lundbeck Case: A Competition Law and Economics Perspective, mimeo.
(Contribution: Jonas Severin Frank 100%)

The fourth essay of the dissertation has the title “Patent Settlements in Europe and the Lundbeck case: A Competition Law and Economics perspective”. The objective of the essay is to analyze European patent settlement policies, particularly the European Commission’s decision in the Lundbeck case, from a competition law and economics perspective and develop recommendations. It takes into account the legal perspective by analyzing case documents, official guidelines as well as discussions in the legal fields as well as the economic perspective by using diverse insights from economic theory about patent settlement assessment. Lundbeck is one of the important reverse payment patent settlement cases in Europe and also has led to a decision of the General Court of the European Union which affirmed the European Commission’s decision. The background of the essay is that in Europe we observe much scrutiny towards patent settlements in recent years. However, we do not find a clear assessment scheme to deal with these agreements but rather see developing policies shaped by the European Commission as well as court rulings. It was therefore the motivation of the essay to analyze if the Lundbeck case was decided correctly and what this means for the broader perspectives and problem fields for patent settlement policies in Europe. The article builds on insights gained in all three previous articles included in the dissertation. It uses insights regarding the U.S. pharmaceutical sector and its institutional framework as well as U.S. antitrust policies towards patent settlements (which was the focus of the first article) to ask what we can learn from the U.S. for Europe. And it uses economic insights on how we should deal with patent settlements (which was a focus of the articles 2 and 3). A central result of the article is that the decision of the European Commission to fine originator firm Lundbeck as well as several generic firms for delaying generic market entry in a violation of competition law, can be supported. The complex case is analyzed on the basis of economic reasoning. A further result is

that the Lundbeck case is special so that drawing conclusions for other cases or case groups is limited. To gain further insights, the article also analyzes the European Technology Transfer Guidelines which explicitly take into account the problems of patent settlements. General problem fields in patent settlement assessment as well as contributions and limitations of the Guidelines are structured and discussed. The essay further asks what we can learn from the U.S. discussion and points to important institutional differences in terms of patent law and pharmaceutical sector regulation which are highly relevant for patent settlement assessment. It becomes evident that patent settlement assessment is so complex that it would require taking into account many different effects and factors. This is also true for quantifying the reverse value transfer and determining its anticompetitive potential. The essay uses arguments from the economic analysis of error costs to recommend a specific structuring of patent settlement assessment. The recommendation distinguishes between using strong presumptions of the anticompetitiveness of settlements with reverse payments and safe harbor rules for settlements without. The article points to perspectives for future research which could produce insights on how to further distinguish different case groups to develop more refined assessment schemes for patent settlements.

The four essays included in this dissertation analyze the problem of patent settlements from distinct perspectives. As pointed out, there also exist links between the essays. This contributes to comprehensively answering the main research question of this dissertation. All in all, it can be stated that the assessment of patent settlements requires an economic analysis of their effects within the institutional framework of the pharmaceutical sector. Consumer welfare, which is the normative criterion, is influenced by patent settlements through different channels of effects, both in terms of its reduction or its improvement. This holds especially if these agreements are seen in the context of problems of the patent system. This dissertation points to relevant factors for assessment decisions for patent settlements and how they relate to the institutional framework, in particular to competition policy.

Essay 1:
Patent Settlements in the Pharmaceutical Industry: An Antitrust Perspective

Authors:
Jonas Severin Frank (Contribution 70%), Wolfgang Kerber (Contribution 30%)

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Jonas Severin Frank and Wolfgang Kerber

Patent Settlements in the Pharmaceutical Industry: An Antitrust Perspective

1 Introduction

In the beginning of 2008 the European Commission (EC) started a sector inquiry in the pharmaceutical industry. The Commission states that particularly generic competition is a key factor in protecting consumer interests by allowing access to drugs and containing costs of public healthcare (EC 2009a, p.2). The pharma sector inquiry was conducted against the background of significant changes in the pharmaceutical sector where the rate of newly introduced drugs has declined and several blockbuster medicine patents, accounting for large total revenue shares, have expired or will soon (ibid., p.3). Originator firms try to countervail this trend by maintaining patent protection on drugs as long as possible and by diversifying their revenue streams (ibid.).

The strategic use of the patent system plays a crucial role since original manufacturers and patent owners try to shield themselves from generic competition. One option for original drug patent owners is the creation of "patent clusters" (including pending patent applications) around a base patent, providing a "multi-layered defence" which makes generic access more difficult after the base patent has expired (EC 2009b, pp. 184). Another possibility is "divisional patent application" where besides the "parent patent" smaller-scope patents are registered which however grant an exclusivity period of their own. Such patent application strategies can create higher uncertainty with respect to pending "divisional" patents (ibid., pp. 193). "Lifecycle strategies" refer to the registration of follow-on patents for already existing drugs. This is also referred to as "evergreening" of patents hindering or delaying generic competition for the original product by the patenting of small, incremental changes to it (e.g. different formulations or dosage forms of the same drug) (ibid. pp. 351). Originators can also try to send credible signals that they will fight patent infringement in courts, esp. with the help of injunctions, and create barriers against market entry for potential entrants (ibid., pp. 199).

Besides such practices, a particularly interesting strategy for impeding generic competition is the use of patent settlement agreements between originator and generic firms. Since the patents of the originator firms might be weak and perhaps found invalid if challenged by generic firms, the ensueing patent litigation can lead to settlements between the parties, in which the originator firms agree to pay the challenging generic firms a considerable amount of money for accepting their patents and therefore delaying their entry into the market (pay-for-delay

agreements; FTC 2010, p. 1, EC 2012b, p. 14 at para. (43)). Whereas settlements in expensive patent suits might generally be deemed as having positive welfare effects (due to the saving of litigation costs), the fact that in some of these patent settlements the patentholder pays large sums to the generic firm raises the suspicion that such "reverse payment" clauses (or other side-deals with similar intentions and effects) might only impede generic competition. The ensueing longer period of high drug prices would harm consumers, whereas the additional profits from this strategy accrue to both the originator and the generic firm.

Therefore, it is not surprising that the European Commission views such patent settlements, in which original manufacturers pay generic competitors for their acceptance of restricted market entry, as problematic from a competition law perspective (EC 2009b, p. 509). This critical stance on patent settlements is supported by findings of a large share of successful patent challenges of generic firms raising the question of the validity of many patents. In its examination of the pharmaceutical sector the EC found that generic manufacturers have won approximately 60% of the lawsuits in the period from 2000 to 2007 concerning secondary patent oppositions (Boards of Appeal decisions encompassed) on which generic firms nearly exclusively focused on.[1] In 15% of these cases the original patent scope was limited by courts (EC 2009a, p. 12), whereas litigation lasts over two years on average for approximately 80% of final decisions taking into account opposition and appeal (EC 2009b, p. 253). Although the EC does not refer to secondary patents as generally going along with lower patent quality, as the patentability criteria are the same (EC 2009a, p. 5), the high percentage of successful generic challenges hints at questionable patent validity in these cases.

The EC therefore conducted a patent settlements monitoring between generic and original manufacturers and released several reports (e.g. EC 2010, para. (1)). Restrictions for generic entry, which the parties agreed on, were found by the EC in nearly half of the settlement agreements between originator and generic firms between 2000 and 2008 while it was mentioned that a high share of those included reverse value transfers from the originators to the generic firms (EC 2009a, p. 13). The Commission estimates that 20% higher savings due to generic entry could have been achieved in contrast to the actual savings that have been generated (see EC 2009a, p. 9). So far the European Commission has not developed a clear policy in regard to patent settlement agreements between originator and generic firms with reverse payments. Currently several investigations take place

[1] Secondary patenting concerns follow-on products, different dosages or related processes of already patented products which can be seen as an attempt to extend the duration of protection of the product family involved (EC 2009a, p. 5, 9 and EC 2009b, p. 253).

with respect to settlement agreements between pharmaceutical firms possibly hindering generic access in cases including Johnson & Johnson and Novartis, Cephalon and Teva, Lundbeck, and Servier (EC 2011a, EC 2011b, EC 2012a). The current presumption in the EU being skeptical towards agreements which include a reverse payment and a restriction of generic entry might become clearer when upcoming final decisions on relevant cases are made.

In the U.S., this problem of patent settlements with reverse payments between originator and generic firms has been the object of intense scrutiny and discussion by antitrust authorities and courts for a much longer time. These agreements, in the U.S, are also strongly influenced by the Hatch-Waxman Act, which intended to provide an appropriate institutional framework for this relationship between originator and generic firms in the pharmaceutical industry and which should promote generic competition. The fact that the introduction of generic pharmaceuticals would lead to much lower prices and therefore increases consumer welfare has also been emphasized by the U.S. Federal Trade Commission (FTC) and the U.S. Department of Justice (DOJ) (FTC 2010, p. 1, U.S. DOJ, 2011, pp. 3). Therefore, in the U.S., patent settlements with restrictions of market entry and reverse payments are expected to considerably increase health care costs, which countervails the original aim of fostering generic entry by establishing their easier access to the market thus providing consumer benefits (Leibowitz 2009, p. 8 cited by Carrier 2009, p. 50 at supra note 82). Therefore, the FTC has used antitrust scrutiny to confront possibly anticompetitive patent settlements in the context of litigation in the Hatch-Waxman framework (FTC 2002a, p. i). However, the policy of the FTC to challenge patent settlements with reverse payments on grounds of their anticompetitive effects due to impeding generic competition has met some resistance in the U.S. courts, which partly upheld the patent settlements as a legitimate instrument for defending patents as long as they do not lead to an extension beyond the scope of the patents. In the U.S., there is an intense debate about the assessment of this kind of patent settlements whose result is still open. The current situation is characterized by a very controversial debate and inconsistent views of competition authorities and courts on this issue. This is highlighted by the fact that last year the Supreme Court has accepted a case of patent settlements with reverse payments[2], which might offer the perspective of a clear resolution how such patent settlements should be decided

[2] The U.S. Supreme Court decided to accept the reverse payment settlement case Federal Trade Commission, Petitioner V. Watson Pharmaceuticals, inc., et al. 2012 on 07.12.2012 (U.S. Chamber of Commerce, 2012) to make a decision as reaction to an FTC appeal to the Supreme Court.

from an antitrust perspective. In the recently published petition to the U.S. Supreme Court for a clarification on this matter, the FTC held that anticompetitive reverse payment agreements are "a recurring question of great economic importance that has divided the courts of appeals" (FTC Petition for a Writ of Certiorari to the U.S. Supreme Court in the case Federal Trade Commission, Petitioner V. Watson Pharmaceuticals, inc., et al., 2012, p. 2) and are estimated to "cost consumers billions of dollars annually" (ibid., p. 11).

Since the experiences and debates in the U.S. might be very helpful for the discussion of patent settlement agreements in Europe, this article will give first an overview about the legal rules in regard to the relationship between originator and generic firms in the U.S. (including the Hatch-Waxman Act) and about the different positions of the competition authorities and courts in regard to patent settlements with reverse payments and restrictions to generic entry. In a second step, the most important arguments in this debate are analyzed from an economic perspective. A crucial insight will be that the effects of patent settlements have to be analyzed under consideration of the interplay of the regulations of the patent law, the Hatch-Waxman Act, the U.S. Food and Drug Administration, and antitrust rules. Finally, some conclusions are drawn in regard to policy implications and further need of research.

2 Pay-for-delay Settlements in U.S. Antitrust Policy

2.1 The Role of the Hatch-Waxman Act

The Drug Price Competition and Patent Term Restoration Act of 1984, also known as Hatch-Waxman Act, created a framework for balancing the tradeoff between maintaining sufficient innovation incentives for originator firms on one hand and enabling generic competition on the other hand (FTC 2002a, p. i; Hemphill & Sampat 2012, p. 327). Its original purpose was to foster generic competition by ensuring an easier market access while at the same time providing incentives for faster generic entry and patent exemptions for research and development. Due to previously existing patent law and regulation under the U.S. Federal Food, Drug, and Cosmetic Act it was difficult for a generic competitor to enter the market. Since 1962, these regulations required brand pharmaceutical companies to show to the U.S. Food and Drug Administration (FDA) additionally to the safety also the effectiveness of the respective drug. The result of this amendment was the necessity of high investments by pharmaceutical companies to get approval for the marketing of a drug. Since also generic suppliers had to comply with these safety and efficiency standards, generic firms had to spend large costs on tests, which were largely redundant due to the fact that the safety and efficiency of the original drug was already shown before (FTC 2002a,

pp. 3). Due to this regulation the market entry of generic suppliers was possibly delayed for years (Carrier 2009, pp. 41, Robinson 2003, pp. 833). Moreover, for potential generic competitors it was not possible to conduct clinical tests until the relevant patents had expired. Thus, the combination of approval procedures of the FDA and patent law led to a dominant role of brand pharmaceuticals in the market and difficult generic entry. However, also the original suppliers had difficulties to recoup their enormous investments as patent protection was de facto shortened due to FDA approval procedures (FTC 2002a, pp. 3). The Hatch-Waxman Act sought to change this situation by putting a bundle of provisions into force.

Concerning the aim to foster generic competition, especially three elements of the Hatch-Waxman Act are relevant: Firstly, under Hatch-Waxman a research exemption was introduced under which it became possible to conduct certain proceedings necessary for an FDA approval of the respective drug without infringement of existing patents. Secondly, for this purpose generic firms got access to trade-secret data of original manufacturers to prove safety and effectiveness of their generic drugs. Thirdly, to maintain innovation incentives for original manufacturers under Hatch-Waxman it became possible to apply for a special exclusivity period compensating for lost time due to regulatory approval for marketing their products (United States Patent and Trademark Office, FTC 2002a, p. 4). These changes to regulatory proceedings clearly indicate that the U.S. Congress sought to balance incentives for research and development for original manufacturers by giving them a powerful patent claim with a chance for compensation for FDA approval time and the promotion of generic access, mainly by enabling competitors to start FDA approval tests already under patent protection and by giving them access to relevant information by original manufacturers.

For a generic competitor to enter the market for a drug several steps can be distinguished. At first the generic company has to file an Abbreviated New Drug Application (ANDA) at the FDA on the basis of the New Drug Application (NDA) of the originator product. As mentioned above the generic firm can use data of the originator to show that the generic drug is safe and effective by attesting it as "bioequivalent" (U.S.C. Title 21 at § 355(j)(2)(A)(iv)). For the question of patent infringement the generic company has to certify one out of four possible paragraphs referring to patent listings in the "Approved Drug Products with Therapeutic Equivalence Evaluations" also called "Orange Book". These listings are part of the filing of the NDA under the Federal Food, Drug, and Cosmetic Act, where the originator company inter alia has to provide information to the FDA about patents covering the original drug (U.S. FDA 2012). On the basis of these "Orange Book" – patents the generic competitor has to certify that (i) the required intellectual property is not filed as patents in the "Orange Book" or (ii)

the required patents in the "Orange Book" have expired or (iii) the approval of the generic will be sought at the date when the required patents in the "Orange Book" have expired or (iv) the required patents in the "Orange Book" are invalid or the ANDA does not infringe them. This statement of the generic company now may trigger certain effects dependent on the respective statement. Paragraph (i) and (ii) statements are not problematic since immediate approval by the FDA is possible. A paragraph (iii) approval is possible after the expiry of the respective "Orange Book" – patents.

However, a certification under paragraph (iv) involves the duty of the generic company to send a notice to the patent holder and NDA-filer showing the grounds why patents listed in the "Orange Book" are invalid or not infringed by the ANDA (U.S.C. Title 21 at § 355(j)(2)(A)(vii)). Subsequently, the originator brand company (patent holder and NDA-filer) has 45 days to file an infringement suit against the generic company. If this suit is not filed in this time, the approval procedure by the FDA continues. In case the suit is filed, this triggers an automatic 30-month stay with respect to the approval of the generic drug by the FDA. The approval process can only be conducted by the FDA, if the 30 month period is over or the invalidity or no infringement of originator patents is determined by a court or the patent has expired before the end of the 30-month stay (FTC 2002a, pp. 5). A second implication of Hatch-Waxman regulation is a 180-day exclusivity period for the generic firm who first files the ANDA based on a certification under paragraph (iv) (FTC 2002a, pp. iv). By giving this exclusive marketing right, generic firms should get a higher incentive to enter the market or to challenge the patent in the first place which is aligned with the original aims of Hatch-Waxman.

2.2 The Positions of Antitrust Authorities and Courts

Although the Hatch-Waxman Act led to a promotion of generic entry, a growing number of settlements in regard to patent infringement suits between originator firms and generic firms emerged.[3] In these settlements, reverse payments from originator to generic firms and agreements about a delay of the entry of ge-

[3] Despite existing antitrust scrutiny in the U.S., a recently published report by the FTC indicates that in the fiscal year 2012 40 settlements of a total of 140 final resolutions of patent disputes "may involve pay-for-delay payments" from the original to the generic manufacturer. Moreover it is shown that, on overall, the numbers of such settlements have increased in recent years (FTC 2013, pp. 1).

nerics could be observed, raising the concerns of U.S. antitrust authorities. Those "Pay for delay" agreements could be interpreted as a sharing of monopoly profits and a "win-win" between originator and generic companies to the detriment of consumers (FTC 2010, p. 1). The FTC estimated that these agreements between original and generic manufacturers have delayed generic market entry by 17 month on average compared to agreements where no reverse payment takes place (FTC 2010, p. 2). As a result costs are estimated to increase for consumers by 35 billion $ over ten years while for the same period their elimination would result in federal savings of 12 billion $. Lesser conservative assumptions, taking into account the expected increase of the governments share of drug costs, led to estimated costs for consumers of 75 billion $ and potential federal savings of 25 billion $ over ten years (Leibowitz 2009, p. 8 cited by Carrier 2009, p. 50 at supra note 82, FTC 2010, p. 6). Due to these effects the FTC began to challenge settlement agreements within the Hatch-Waxman framework since March 2000 (Bulow 2004, p. 145). The FTC regards such settlement agreements with substantial reverse payments, which clearly delay generic entry without a different motive (Brankin 2010, p. 24), as unlawful. However, the U.S. courts were in parts very critical to these challenges of the FTC, and also upheld these patent settlements. All in all it becomes apparent that there exist different opinions of competition authorities and courts but also ambiguity with respect to decisions of different courts at different levels of jurisdiction about the topic.

The case Schering-Plough, involving a settlement between original manufacturer Schering and generic supplier Upsher-Smith of June 1997, shows these difficulties regarding challenges of the FTC with respect to reverse payment agreements. The parties entered into a settlement after Upsher-Smith was first to file an ANDA under paragraph (iv) certification. Subsequently, Schering sued for infringement of its patent for the original drug version K Dur 20 expiring in 2006.[4] The settlement shortly before the start of the trial involved a commitment by Upsher-Smith not to market the generic version until September 2001 and to grant Schering several unrelated licenses, whereas Schering agreed to pay Upsher-Smith an amount of 60 million $. Similarly, Schering settled with generic manufacturer ESI Lederle which also filed an ANDA under paragraph (iv) certification.[5] The agreements were challenged under Section 5 of the FTC Act, while there was a settlement between ESI Lederle and the FTC (Bulow 2004, pp.

[4] The litigation is also referred to as "K Dur Antitrust Litigation" (U.S. DOJ 2011).
[5] The settlement involved ESI Lederle`s commitment to not market their generic until January 2004 for a payment of 15 million $ from Schering. Additionally, a grant of unrelated licenses by ESI Lederle was included for another 15 million $. (Bulow 2003, pp. 153).

153).[6] The Administrative Law Judge found the agreement between Schering and Upsher-Smith lawful under the rule of reason, because there were pro-competitive elements, especially the earlier generic market entry and a resolution of patent litigation. The payment of Schering was accounted to the unrelated license granted by Upsher-Smith. The FTC`s appeal, inter alia including the argument that the reverse payment was too large for only accounting for the unrelated license grant by Upsher-Smith, was turned down by the 11th Circuit court decision, mostly arguing in a similar way like the Administrative Law Judge. The court argued that the valid patent was a right to exclude, that the patent scope was not extended while the settlement terms were a result of the patent claim and that any impediments of competition subject to the agreement were a necessary element of the settlement itself (Carrier 2009, p. 54). The FTC subsequently sought review of the Supreme Court on the subject who refused to make a decision (ibid, pp. 55).

This case shows the importance of the presumption of patent validity which was crucial for the conclusion of the court in not finding an anticompetitive agreement: An original manufacturer should not be subject to antitrust liability while having a valid patent (35 U.S.C. § 282 2006 cited by Carrier 2009, p. 62 at supra note 173.). It is a general tendency that courts in the U.S. have focused on the social and private gains of patent settlements like reduction of uncertainty or litigation costs (Holman 2007, pp. 499, FTC 2002a, p. 25). The contrary argument of the FTC is rather in favor of consumers having a right of protection against settlements diametric to their interests (Carrier 2009, p. 63). The U.S. Courts of Appeal held that reverse payment settlements are accepted, if they delay generic entry within the scope of the actual patent grant and only with regard to possibly infringing products.[7] However, patent settlements resulting in a prevention of generic entry beyond the patent scope, e.g. by preventing the entry of non-infringing products, are treated as illegal per se.[8]

While the FTC regards substantial reverse payments with the motive to delay generic entry as being a critical issue because the original manufacturer buys

[6] Section 5 of the FTC Act declares as unlawful: "Unfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce (…)" (United States Code U.S.C. Title 15 at § 45, (a) (1)).

[7] See Schering-Plough Corp. v FTC, 402 F.3d 1056 11th Cir. 2005 cert. denied, 126 S. Ct. 2929 2006; In re Tamoxifen Citrate Antitrust Litig., 466 F.3d187 2nd Cir. 2006 and In re Cardizem CD Antitrust Litig., 332 f.3d 896 6th Cir. 2003, cert. denied, 543 US 939 2004 cited by Brankin 2010, p. 24 at supra note 9.

[8] See In re Cardizem CD Antitrust Litig., 332 f.3d 896 6th Cir. 2003, cert. denied, 543 US 939 2004 cited by Brankin 2010, p. 25 at supra note 12.

time for monopoly profits diametric to consumer interests, some courts rather apply a presumption of patent validity with the consequence that reverse payment settlements are assessed positively if there is earlier generic entry and resolution of litigation. Thus, the main difference between these two lines of arguments lays in the presumption of validity. If a patent is assumed to be valid, then every agreement, even if it includes some restrictions to competition, is positive, if it leads to earlier generic entry. However, if patent validity is assumed to be questionable, every agreement including a substantial and not justified reverse payment for restricting generic entry might be anticompetitive, because only a settlement without such payment and earlier generic entry correctly accounts for this questionable nature of patent validity. Following this line of argument, the outcome of the settlement agreement for consumers should account for the possibility of the patent not being found valid (Shapiro 2003b, p. 395). As consumers can expect the chance of patent invalidity in a paragraph (iv) litigation, the result of a (reverse payment) settlement is a signal for the perceived patent strength of the parties and should correctly take into account the likelihood of the patent`s invalidty.[9] This means that a substantial reverse payment indicates high doubts about the validity of the patent and should not go along with substantial entry restrictions (Dolin 2011, pp. 322).

The U.S. Department of Justice (DOJ). which also can enforce antitrust rules, was involved in the K-Dur Antitrust litigation (in the role of Amicus Curiae as an expert counsel in court). Also the DOJ cares about challenges of patent settlements in the pharmaceutical sector as they strongly affect consumer welfare (U.S. DOJ 2011, p. 1). The DOJ has had a standpoint in between the arguments of the FTC and decisions which have been made by U.S. courts (Brankin 2010, p. 26). In the K-Dur statement, the DOJ held that (A) private patent settlements should be subject to antitrust scrutiny, (B) they should not be held per se illegal while the rule of reason is the appropriate approach to assess reverse payment settlements in balancing efficiencies and anticompetitive effects, (C) settlements involving a payment which leads to a withdrawal of a challenge of patent validity or infringement “are presumptively unlawful” and that (D) defendants can show that a settlement does not aim at the exchange of money for a reduction of competition (U.S. DOJ 2011, pp. 10).

The DOJ makes clear that settlements which restrict generic entry by ending patent challenges prevent the risks of litigation for the patent holder to the detriment of price competition in markets where the patent holder has market power

[9] FTC Petition for a Writ of Certiorari in Schering-Plough Corporation, et al. 2005, supra note 244, at 17-19 cited by Holman 2007, p. 533 at supra note 251, 252.

which may strongly be reflected by a large reverse payment. A clear distinction is made between restrictions stemming from litigation and such restrictions stemming from settlements (ibid., pp. 17 f.). Also mentioning the position of the FTC, the DOJ notes that the amount of the reverse payment in question has to be assessed. If this amount accounts for avoided litigation costs or for different expectations of the parties of winning at trial, such a payment should be seen as rather unproblematic (Janis/Hovenkamp/Lemley 2003, Crane 2002). On the other hand, larger payments reveal the perception of the patent holder that the patent could be found invalid or not infringed and therefore suggests the intention to avoid competition. As an example, the DOJ holds an agreement as anticompetitive where parties ex ante assess the probability that a patent is valid above 50 percent while agreeing on a settlement not allowing for generic entry until the expiry of the patent. Even a reverse payment with earlier generic entry than actual patent expiry is not necessarily seen as adequate defense by the DOJ as long as the earlier entry date and other parts of the deal do not reflect the parties' assessment of the probability that generic entry could have been allowed earlier, if the patent was litigated (U.S. DOJ 2011, pp. 27). For the DOJ, it is therefore in society's interest that the agreement reflects the parties' respective perception of patent invalidity or non-infringement, which is also described as bargaining power, in the form of the agreed-on entry date to prevent "undeserved monopolies" (ibid, pp. 22 f.). Reverse payments, if part of such agreements, should be assessed in connection with the agreed entry date or other restrictions.

During the Obama presidency a change in the leading position of DOJ`s antitrust division led to a convergence of the positions with the FTC (U.S. DOJ 2010 cited by Brankin 2010, p. 26 at supra note 23). Accordingly, the DOJ supported the position of the FTC in an appeal to the U.S. Supreme Court concerning a reverse payment settlement case (see below).[10] The DOJ looks at the anticompetitive potential of settlement agreements exchanging money for not challenging patents and delaying generic entry, while holding that a shielding rule for such agreements would not be positive for competition and innovation.[11] The DOJ argues that such a presumption of patent validity should not be the legitimation for a restrictive application of antitrust rules of the Sherman Act (U.S. DOJ 2010, p. 7).

[10] See FTC Petition for a Writ of Certiorari to the U.S. Supreme Court in the case Federal Trade Commission, Petitioner V. Watson Pharmaceuticals, inc., et al. 2012 henceforth referred to as FTC Petition for Certiorari 2012.

[11] See U.S. DOJ in its Brief Amicus Curiae of The United States in Support Of Rehearing In Banc, Arkansas Carpenters Health and Welfare Fund et al v Bayer et al.

The U.S. Supreme Court has recently decided to make a decision concerning a reverse payment settlement case (Watson Pharmaceuticals) which can be expected to result in more distinctiveness on this topic.[12] In its appeal to the Supreme Court, the FTC rejects the opinion of the Courts of Appeals For the Eleventh Circuit who denies antitrust scrutiny as long as the competition constraints fall within the patent scope and no other violations take place.[13] The FTC views the argument that reverse payments are lawful as long as they are not resulting in a larger restrictive power than granted due to the patent scope as erroneous since this would forestall the actual validity of the patent, yet to be decided. The FTC instead states that "the Third Circuit's approach, which treats reverse payment agreements as presumptively anticompetitive, reflects the appropriate balance between the competing interests implicated by such agreements" (FTC Petition for Certiorari 2012, p. 21). The FTC emphasizes that defendants often win in patent litigation and a victory of the patent holder should not be a general presumption in the Hatch-Waxman framework (FTC Petition for Certiorari 2012, p. 11). On the other hand, the FTC makes clear that not every reverse payment agreement should be seen anticompetitive per se as efficiency effects have to be acknowledged.[14] It seems that the decision of the Supreme Court in this matter could be a landmark for the future assessment of reverse payment settlements in the U.S. The split positions of different lower courts ranging from an assessment of such agreements of per se illegality close to per se legality (Leibowitz 2009, p. 9) in combination with the opinions of the FTC and the DOJ seems to be a call for more clarity which can possibly be restored by the Supreme Court. The fact that the Supreme court did accept the FTC`s appeal clearly indicates that the matter is important and that the court wants to decide on this subject.

[12] The U.S. Supreme Court decided to accept the case Federal Trade Commission, Petitioner V. Watson Pharmaceuticals, inc., et al. 2012 on 07.12.2012 (U.S. Chamber of Commerce, 2012) as reaction to the FTC Petition for a Writ of Certiorari 2012.

[13] The Court Of Appeals For The Eleventh Circuit argued in related cases that "absent sham (patent) litigation or fraud in obtaining the patent, a reverse payment settlement is immune from antitrust attack as long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent" (The United States Court Of Appeals For The Eleventh Circuit cited by FTC Petition for Certiorari 2012, p. 2).

[14] In this context the FTC holds "a so called 'Quick Look' or 'truncated rule of reason' analysis" as appropriate where compensating efficiency advantages in a presumably anticompetitive reverse payment-settlement have to be created by the settling parties (Blair/Cotter 2002, pp. 534, FTC Petition for Certiorari 2012, pp. 23 citing K-dUR, 686 F.3D AT 209 and FTC V. Indiana Fed'n of Dentists, 476 U.S. 447, 459 (1986)).

3 Patent Validity, Patent Settlements, Reverse Payments, and the Regulatory Framework: An Analysis

3.1 Patent Validity and Patent Challenge within the Regulatory Regime of the Pharmaceutical Industry

From an economic perspective, it is clear that in the pharmaceutical industry originator firms need patent protection for ensuring sufficient incentives for carrying out their cost-intensive and risky R&D. After the expiry of patent protection, other competitors (generic firms) should be able to enter the market immediately, leading to lower prices (at the level of average production costs) and an increase of consumer welfare. Any kind of agreements between originator and generic firms, which through a payment to the generic firms would lead to a de facto prolonging of the monopoly of the originator firms beyond the duration of the patent, would be an anticompetitive (cartel) agreement and therefore prohibited both under EU and U.S. antitrust rules. This is not controversial. The current controversy, esp. in the U.S., refers to the very different problem that the patent in question might not be valid in the first place. If the originator firm has gotten a patent, which never should have been granted by the patent office, then the originator firm is not entitled to its exclusive rights and enforcing it against other pharmaceutical firms restricts competition and harms consumers (as any other kind of monopoly). Therefore, the position of some U.S. courts that such patent settlements are no problem as long as they remain within the scope of the patent is not relevant, because the validity of the patent itself is disputed.

In the last decade, the insight has increased that the patent law regime (both in the U.S. and the EU) suffers from serious defects.[15] In the meantime, there is a broad consensus that often patent claims are not precisely defined, leading to the problem of overlapping patents and patent thickets (Shapiro 2001, Gilbert 2009, p. 2). In addition to that, experience shows that the requirements, e.g., in regard to the necessary "inventive step", have been lowered (Harhoff et al. 2007, p. 250). Therefore, too many patents for often only minor inventions have been granted, which endangers competition and stifles innovation. Part of the problem is that the patent offices lack sufficient resources to carry out solid and well-

[15] This argument is referred to in a body of literature e.g. in Shapiro 2001, p. 121, Gilbert/Weinschel 2005, pp. 1, Leaffer 2010, p. 143 at supra note 9, 10 citing Bessen/Meurer: Patent Failure: How Judges, Bureaucrats And Lawyers Put Innovation At Risk, 1-25, 2008 and Jaffe/Lerner: Innovation And Its Discontents: How Our Broken Patent System Is Endangering Innovation And Progress, And What To Do About It 6, 50, 2004.

researched examinations of patent applications (Gallini 2002, p. 150, Shapiro 2003b, p. 392, Farrel/Merges, 2004, pp. 944). In the meantime, both economic and legal scholars of patent issues are well aware of these problems. Therefore, the assumption that all patents granted by the patent offices are justified and should be deemed as unquestionably valid, cannot be upheld any more.

One important response within the patent law regimes itself is to strengthen the internal mechanisms for screening and sorting out weak and non-defendible patent rights granted by patent offices by challenging them legally (e.g., through opposition procedures). The patent law regime relies in this respect on a private enforcement mechanism for challenging unjustified patent rights. Therefore, the patent law regime itself has a built-in mechanism for correcting erroneous grants of patents, whose effectiveness is however questioned by many scholars, leading to wide-spread claims for strengthening it. Consequently, also the patent laws do not and should not assume that all patents granted by patent offices are justified (Harhoff et al. 2007, pp. 276). In regard to the relation between originator and generic firms in the pharmaceutical industry, the problem that there might be unjustified (and therefore invalid) patents has been explicitly addressed both in the Hatch-Waxman Act as well as the regulations in regard to the FDA. It is very important to understand that the rules for granting, defending and challenging patents as well as using them in the pharmaceutical industry are the result of a comprehensive legal framework consisting of patent law, the Hatch-Waxman Act, the rules for the approval of new drugs by the FDA as well as other laws, as, e.g., antitrust rules (see also Hovenkamp 2004, pp. 14).

In the following, it is analyzed how the Hatch-Waxman Act in combination with FDA rules intentionally influences the incentives for originator and generic firms. This should simultaneously increase incentives for (true) pharmaceutical innovations and protect (generic) competition by providing additional explicit incentives for challenging weak patent rights, which should improve the effectiveness of the private enforcement system in regard to the invalidation of unjustified patent rights. Our main argument will be that patent settlements with reverse payments between originator and generic firms can weaken the effectiveness of this private enforcement system leading to anticompetitive effects by restricting the market entry of generic firms.

The Hatch-Waxman Act and its reform aimed at creating a framework to facilitate generic entry in the pharmaceutical industry (FTC 2002a, Executive Summary and Legislative Recommendations). Under the act generic competitors can enter the market without the need to reproduce clinical safety studies in case of "bioequivalence" of the drugs concerned and by challenging existing patents, which beforehand was difficult due to previously existing patent law and regulation (U.S.C. Title 21 at § 355(j)(2)(A)(vii) and FTC 2002a, pp. 3). So this act tried to balance innovation incentives of original manufacturers with promoting

easier access to the market (Carrier 2009, pp. 41, Robinson 2003, pp. 833). What are the rationales and problems of the 30-month stay period for generic entry and the 180-day exclusivity period for generic drugs as the most important elements of the Hatch-Waxman framework?

The automatic 30-month prevention of market entry by the generic competitor is triggered in the case of a challenge of an existing patent (paragraph (IV) certification) followed by a subsequent infringement suit of the original patent owner. In this period, entry is only possible, with respect to an approval by the U.S. Food and Drug Administration, if the relevant patents expire during the time or a court decides that the respective patents are invalid (FTC 2002a, pp. 5). On one hand, this regulation acknowledges the position of the patent holder, because irrespective of the patent strength there exists protection against market entry of the generic firm for the length of patent litigation but for a maximum of 30 months. On the other hand, it also leads to a stronger position of generic competitors as they have the chance to enter the market under these provisions after 30 months irrespective of active patents. This could be interpreted as an attempt to mitigate the problem that litigation can last much longer than 30 months. In that respect this 30-month rule leads to a new balance between originator and generic firms in regard to the problem of legal uncertainty in respect to the validity of the patents but also the interests of the generic firms and the public for generic competition. What is particularly interesting is the fact that this rule does only apply to those patents which have been registered as relevant for the drugs by the originator firms in the "Orange Book" of the FDA. This confirms our argument that Hatch-Waxman rules, FDA rules, and patent law rules constitute an integrated institutional framework for the relation of originator and generic firms in the pharmaceutical industry.

A very interesting but also to some extent problematic rule is the 180-day exclusivity period in regard to an approval for market entry by the FDA for the generic firm that - under paragraph (IV) certification - challenges the patents of the originator firm first. It is clear that such a competitive advantage should give generic firms larger incentives for challenging the existing patents in order to avoid an underprovision of patent challenges (McDonald 2003, pp. 69, 72, and Shapiro 2003a, pp. 70). From an economic perspective the problem can be described as a public good problem with its ensueing free-rider problems (Farrell/Merges, 2004, pp. 952). Without the exclusivity period, all generic firms could enter the market after a court decision declared the patents invalid, which would make it hard for the challenging generic firm to recoup its litigation costs and risks, and therefore reduce considerably their incentives for challenging the patents in the first place. It is important to understand that the weeding out of unjustified patents by challenging them is a public good, which benefits all generic firms and all consumers of these drugs. Since this task is not fulfilled by a public agency

(paid by the tax payer) but left to a private enforcement system, its effective implementation requires appropriate incentives for private actors, i.e., here generic firms. Therefore, this 180-days limit to competition among generic firms can be seen as necessary for incentivizing patent challenges by generic firms (similar to the acceptance of patent monopolies over a certain time for the prospect of the development of new products and innovation).

If we see the Hatch-Waxman Act as an instrument for strenghtening the incentives for challenging unjustified patents through generic firms, then ensueing patent settlements between the patent holders and generic firms might not only lead to efficiency advantages through saving of litigation costs and reducing legal uncertainty (FTC 2002a, p. 25), but might also undermine the entire effectiveness of the private enforcement system in regard to challenging weak and unjustified patents. Patent settlements with large payments from originator to generic firms can be interpreted as the buying off of the challenges to unjustified patents, which would endanger the generation of the public good of weeding out weak patents. As a consequence, the public and private benefits of the parties to such a patent settlement can diverge dramatically (FTC 2010, p. 1). Therefore, it is justified to ask to what extent and under what conditions patent settlements should be allowed in the comprehensive legal framework consisting of the Hatch-Waxman Act, the FDA regulations, the patent law, and antitrust rules.

Independent from this crucial question, which will be discussed deeper in the next section, the specific rules of the Hatch-Waxman Act influence not only the incentives of originator and generic firms but also the allocation of bargaining power between both: Since a patent holder faces the risk that the patent is invalidated in court and that litigation lasts longer than 30 months allowing for generic entry, the scope for settlements is significantly larger. Thus, Hatch-Waxman provisions foster generic challenges and settlements by re-allocating the bargaining positions of the parties, which also has an impact on the chances of the originator firms to enforce their patents as an exclusivity right over the entire patent duration. A specific problem with the provisions of the Hatch-Waxman Act is that the 180-days exclusivity period for the first generic firm which has filed the ANDA aligns the incentives of the patent holder and the challenger in regard to upholding the validity of the patent in a collusive settlement (with reverse payment), because this will give the generic firm a competitive advantage in comparison to other generic firms (Bulow 2004, p. 164, Dolin 2011, p. 283).

Settlement agreements with generic firms are generally possible if the patent holders can win more in paying the generic firms for their lost earning from delayed entry. Or, in other words, if the generic firm`s potential profits from entry are less than the actual monopoly profits of the patent holder, which should normally be the case if lesser profits result after generic entry (Brankin 2010, p. 25.). If such practices restrict entry to a larger extent than the actual patent scope,

then these settlement agreements clearly have anticompetitive effects (but this is not controversial). If, however, patent validity is questionable, patent settlements can be regarded as anticompetitive even if they lead to an earlier entry than original patent expiry date. This is the case if the parties share higher revenues in comparison to profits which would occur in a state of ongoing litigation with courts deciding to restrict the exclusionary power of the patent conditional on the probability that this actually happens (Shapiro 2003b, p. 395). Therefore a part of the literature claims that a questionable patent validity should lead to earlier or extended competition on behalf of consumers based on the probability that the patent is invalid (McDonald 2003, pp. 69, 72 citing Shapiro 2001 at supra note 7) where the updated version is Shapiro 2003b; Shapiro 2003a, pp. 70). In the literature this is referred to as the probabilistic character of patent rights.[16]

The combination of the patent law regime, antitrust rules, the FDA as drug authorization agency, and the Hatch-Waxman legislation has the function to establish a framework where patent challenges are an inherent part of the system itself and which offers the right incentives for the challenging of weak patents. The Hatch-Waxman framework with its original aim to foster generic entry has however led to an environment where patent settlements can stifle the benefits of patent challenges in earlier generic entry. This is especially the case if originators and generics agree on delaying or restricting market entry while at the same time the quality of patents is low or their validity is questionable. In this respect, pay-for-delay patent settlements can make the private enforcement system of challenging unjustified patents ineffective. Since the incentives to challenge patents or to engage in settlements is determined by the overall design of the patent regime, Hatch-Waxman Act, antitrust rules and the role of drug authorization agencies, it is necessary to understand sufficiently the interplay between these different sets of regulations for the correct assessment of patent settlement agreements. At the same time, this also suggests that solutions for these problems can be sought in all these different sets of rules (Janis/Hovenkamp/Lemley 2003, pp.1756). Therefore, in the U.S., it can be thought about introducing limitations to patent settlements through a modification of the Hatch-Waxman Act and/or FDA regulations, through different decisions of the courts within patent law, and also - and this has been done by the FTC - through application of the antitrust rules. In the following section, we will focus only on the last approach for solving this problem. It should be remarked that it is not the first time that competition law has to step in, because the patent law regime does not seem ca-

[16] Probabilistic patent rights are e.g. discussed in Ayres/Klemperer 1999, Leffler/Leffler 2003, McDonald 2003, Shapiro 2003a, Lemley/Shapiro 2005.

pable of solving its own inherent problems, here in regard to the huge problems of legal uncertainty in regard to the validity of patents due to low quality of the assessment of patent applications.

3.2 The Assessment of Patent Settlements from an Antitrust Perspective

In the last section, it was clarified that patent settlements between originator and generic firms in the pharmaceutical industry can lead to anticompetitive effects, because they can be used for protecting unjustified patent rights, leading to illegitimate monopoly positions. There is also consensus that settlements can have considerable efficiency advantages due to saving of litigations costs and the benefits of legal certainty. However, this general benefit of settlements cannot immunize them from antitrust scrutiny, if these settlement agreements lead to considerable negative effects on third-parties, as, e.g., consumers of drugs and health care providers. The difficult problem is under what conditions these patent settlement agreements have to be viewed as anticompetitive and therefore violate antitrust rules. The discussion has mostly focussed on patent settlement agreements with large reverse payments and restrictions of generic entry. Both the U.S. and European competition authorities and many scholars suggest that these settlements are the most problematic. But it is an open question whether a rule of per se illegality, a rebuttable presumption of illegality or a rule of reason approach, which would analyze the settlements on a case-by-case approach, should be applied (see also Janis/Hovenkamp/Lemley 2003, pp. 1728). Beyond that, also other patent settlement agreements might be problematic under certain circumstances.

In its pharma sector inquiry the European Commission distinguished between different groups of patent settlements between original and generic manufacturers. The first category contained agreements with no restrictions on generic entry (A-type agreements), whereas in the second category such restrictions were present (B-type agreements). The EC distinguished such generic entry restricting agreements further into those including a value transfer (type B 2), meaning a reverse transfer from original to generic firm, and those where this is not the case (type B 1) (EC 2010, paras. (11), (15)). For the Commission type A-agreements, which are not restricting generic entry, are per se unproblematic from a competition law perspective. Type B 1-agreements, i.e., those restricting entry without a value transfer, are normally regarded unproblematic except specific conditions as e.g., settlements which restrict generic entry beyond the patent scope. For B 2-settlements, restricting generic entry and including a value transfer from original to generic firms, the highest antitrust scrutiny is demanded. However, the Commission states that not all of these B 2-type agreements are incompatible with EU Competition Law but should be assessed on a case by case basis taking into ac-

count market characteristics or the value transfer itself (ibid., paras. (12)-(14)). The Commission in its 3rd Settlement Report, covering all patent settlements in 2011, concludes that the monitoring itself has not hindered the occurrence of settlements as there is an increasing trend of such agreements in the EU, similarly to the U.S. (FTC 2013, pp. 1). Moreover it is stated that most of them, 89%, are typically not problematic from a competition law perspective, but that ongoing scrutiny is needed since the number of type B 2-settlements have increased (EC 2012b, pp. 15). There can be no doubt that the distinctions of the European Commission in these different types are helpful, although it might be worthwhile to ask whether type A-agreements can never be anticompetitive or to discuss in more detail, under what conditions patent settlement agreements with restrictions to generic entry but without value transfer might be really unproblematic. However, in the following we will focus primarily on the most critical category of patent settlement agreements with restrictions to generic entry and reverse payments.

From a competition policy perspective, patent settlements between originator and generic firms might have both welfare-enhancing efficiency advantages and welfare-reducing anticompetitive effects. The most important efficiency advantages are (1) the saving of (potentially very high) litigation costs due to long and expensive patent litigation, and (2) the benefits of reducing the (often large) legal uncertainty in regard to the validity of patents, which might accrue not only to the patent holder, but also to the challenging generic firms and even to other firms (FTC 2002a, p. 25, Leffler/Leffler 2004, pp. 38). Both of these efficiency advantages might be large and this is also the reason why courts usually support settlements. The most important anticompetitive effects have already been discussed sufficiently in previous sections: Patent settlements with reverse payments might allow the holders of weak and unjustified patents to defend their unjustified monopoly positions, either for the entire patent duration or at least for a certain period until the generic firm is allowed under the agreement to enter the market. In both cases the pharmaceutical firm with the patent reaped unjustified monopoly profits and generic competition was restricted, leading to huge losses for consumers and the public due to too high prices. It should also be kept in mind that these patent settlement agreements are horizontal agreements between direct competitors which can often only be justified by the existence of valid patents (Janis/Hovenkamp/Lemley 2003, pp. 1721). What about the argument that these patent settlements might lead to more innovation, because they might allow pharmaceutical firms to better defend their patents? On first sight, this looks like an argument that would end up on the efficiency side in this discussion (Hemphill 2006, p. 152). However, this is not at all clear: From an economic perspective, we only want to give incentives in regard to R&D in regard to true innovations. Therefore, increasing the incentives for getting weak and unjustified

patents by improving the chances for defending those patents, provides wrong incentives and has welfare-decreasing and therefore anticompetitive effects. If the patents are justified, then the shielding of patents through patent settlements might have positive efficiency effects. The crucial main reason for all these problems is the legal uncertainty, which follows from the low quality of the patent system, which is not capable to distinguish in a clear and fast way between justified and unjustified patent rights (either through the patent office or through courts).

It is not possible here to present a comprehensive discussion of all the relevant arguments and assessment criteria of this kind of patent settlement agreements. Our main claim is that there are many open questions and therefore also a lot of need for further research in order to derive well-informed and solid policy recommendations. In the following, we want to hint to some of these questions.

From a law and economics perspective, the efficiency arguments of settlements with reverse payments depend crucially on information about the assessment of winning probabilities of the patent holder and their generic challenger. Since such information is hard to ascertain, it might be difficult to assess whether the reverse payment might be considerably higher than what could be expected from a simple settlement agreement for saving litigation costs. The assessment of patent settlements and the design of regulations in the U.S. can also be interpreted as an attempt to use the parties' assessment of patent validity as a proxy for the factual validity probability (O'Rourke/Brodley 2008, p. 19). The parties' behavior concerning the decision to challenge or not and to agree on certain terms might be interpreted as a signal reflecting their own perceptions of patent validity. This problem can lead to a discussion about mechanisms for revealing this private information or to attempts of competition authorities and/or courts to assess directly the probability of the validity of patents. All of this needs much more analysis and discussion. Beyond that, it can also be asked whether there are more kinds of important efficiency arguments which would support the legality of these patent settlements with reverse payments and/or restrictions to generic entry.

Another broad field of questions refers to the problem that the assessment of these patent settlements as well as the rules for allowing or prohibiting them under certain conditions have to take into account the interplay between the different sets of rules (as specific rules as the Hatch-Waxman Act, patent law rules, FDA regulations etc.), which constitute the comprehensive institutional framework for innovation and generic competition in the pharmaceutical industry and have an impact on its overall effectiveness and welfare implications. One example might be the interplay between rules for the (il)legality of patent settlements and rules ensuring a competitive advantage for the first challenging generic firm (as the 180-day exclusivity period in the Hatch-Waxman Act). A prohibition of

patent settlements with reverse payments (which exceed the expected litigation costs) might lead to the problem that generic firms might have fewer incentives for challenging weak patents, because profitable patent settlements with the patent holder are not possible. Therefore, prohibiting settlements with reverse payments might also weaken the effectiveness of the private litigation system for weeding out weak patents through challenging patents (Dolin 2011, p. 319). But this also depends crucially on the fact, whether only one or many generic firms could enter the respective market. If there are multiple generic firms, then patent settlements with reverse payments with anticompetitive effects might be difficult, because the patent holder would have to pay all potential challengers.[17] Therefore, the public good problem for the incentives to challenge weak patents turns up again for the patent holder, if the patent shall be defended against all challengers. This implies that the exclusivity rule for the first challenging firm, which should help to incentivize patent challenges, leads at the same time to larger incentives for anticompetitive patent settlements with reverse payments. Therefore, the probability and effects of patent settlements might depend much on the existence of other rules within this comprehensive institutional framework. This implies that much more research is necessary to understand the interplay between these different sets of rules.

However, this also means that in the European Union with its (to some extent) different patent law systems and different procedures for the approval of drugs, the effects of patent settlement agreements might differ from the U.S. system (with the specific rules of the Hatch-Waxman Act). Therefore, we should be cautious about a direct transfer of the results of the U.S. discussion to the European Union. Rather it is necessary to study the effects of different types of patent settlements and the impact of their prohibition or clearance in the context of the specific European institutional framework in respect to the rules for granting and challenging patents and the rules for the approval of new drugs in Europe. It can be expected that the competition policy conclusions in respect to patent settlements agreements in the pharmaceutical industry might be different to a certain extent.

There might also be differences between the U.S. antitrust law and European competition law in regard to the question of the recommendability of using a per se illegality rule for certain kinds of patent settlements, or presumptions about legality or illegality, which might be rebuttable or not. For the most likely anti-

[17] See Hemphill 2006, pp. 126, Hovenkamp 2004, p. 25 cited by United States Court of Appeals for the Eleventh Circuit in the case Federal Trade Commission, Petitioner V. Watson Pharmaceuticals, inc., et al., no. 10-12729, Apr. 25, 2012, pp. 35a.

competitive type of patent settlements with large reverse payments and restrictions to generic entry, the debate focusses on the question whether there should be a presumption of illegality, which, however, might be rebuttable by proving efficiency advantages. Despite all the above-mentioned need for more research, such an approach might be recommended given our current knowledge (see also Janis/Hovenkamp/Lemley 2003, pp. 1759, Ponsoldt/Ehrenclou 2006, pp. 57). However, it is not clear whether the difference to a cautious case-by-case approach might be large. The problem is that the parties of the patent settlement agreements, as also the case Schering-Plough has shown, have ample opportunities to make a variety of complex side-deals (e.g., through lower fees of licensing other patents or allowing earlier generic entry for other drugs) in order to conceal the reverse payment or at least its size. Therefore, it might be difficult for competition authorities and courts to identify such types of agreements (Brankin 2010, p. 27, Hemphill 2009, pp. 663 cited by U.S. DOJ 2011, pp. 24 at supra note 10). Thus, even if specific rules are found and possibly boundaries for the amount of value transfers in combination with different entry dates are established, it might be necessary to analyze these settlements on a case-by-case basis to identify the problematic ones.

4. Conclusions

The question how to assess patent settlements between originator and generic firms in the pharmaceutical sector has raised much attention in the EU and the U.S. The competition authorities and many legal and economic scholars are right to claim that especially a certain type of patent settlements, i.e. those with large reverse payments and restrictions to generic entry, might have large negative effects on consumers and public health care, and therefore raises strong antitrust concerns. The main problem is that originator firms might have weak patents, whose challenging by generic firms might be bought off by patent settlements with large payments to the challenging generic firms. Therefore, firms with weak (and ultimately invalid) patents might be able to defend unjustified monopoly positions through patents, which should not have been granted in the first place, by sharing these monopoly profits with the settling generic firms. Large and otherwise unjustified reverse payments in patent settlements can be seen as a strong sign for the parties' doubts concerning the validity of patents. In this article, we used the U.S. example to show that the entire regulatory framework, consisting of the Hatch-Waxman Act, patent law, drug approval proceedings and antitrust rules, and the interplay between these rules, are crucial both for the correct incentives for challenging and weeding out unjustified patents and for assessing properly, under what conditions patent settlements between originator and gener-

ic firms are anticompetitive, and therefore violate antitrust rules. However, the academic discussion as well as the U.S. experience show that there are many open questions which require much more research. This refers especially to the interplay between the different sets of rules within the entire regulatory framework and to the assessment criteria for distinguishing efficiency-enhancing and anticompetitive patent settlements. Therefore, it is not surprising that so far both in the EU and the U.S. no clear and well-established policy exists how these patent settlements in the pharmaceutical industry should be dealt with.

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Essay 2:

Patent Settlements in the Pharmaceutical Industry: What Can We Learn from Economic Analysis?

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Patent Settlements in the Pharmaceutical Industry: What Can We Learn From Economic Analysis?

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Abstract

Patent settlements between originator and generic firms in the pharmaceutical industry have been challenged by antitrust and competition authorities in the U.S. and the EU. Particularly settlements with large "reverse payments" to generic firms raise the concern of collusive behaviour for protecting weak patents and delaying price competition through generic entry and therefore harming consumers. However, it is still heavily disputed under what conditions such patent settlements are anticompetitive and violate antitrust rules. This article scrutinizes critically what economic analysis has so far contributed to our knowledge about the effects of these patent settlements and the possible rules for their antitrust treatment. An important claim of this paper is that the problem of patent settlements can only be understood, if we analyze it not only from a narrow antitrust perspective but also take into account its deep interrelationship with the problems (and the economics) of the patent system. Therefore we identify three different channels of effects, how patent settlements can influence consumer welfare: (1) price effects, (2) innovation incentive effects, and (3) effects via the incentives to challenge weak patents. The paper critically analyzes the existing economic studies and identifies a number of research gaps, especially also in regard to tradeoffs between different effects. It suggests that policy solutions for these patent settlements should also be sought in combination with patent law solutions.

Keywords: Patent settlements, probabilistic patents, weak patents, pharmaceutical industry, generic competition

JEL classification: K40, L40, O34

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1. Introduction

Patent settlements between originator firms and generic firms in the pharmaceutical industry have been one the most disputed topics in competition and antitrust law discussions in recent years.[1] Particularly patent settlements with "agreed entry dates" in combination with "reverse payments" to generic firms ("pay-for-delay") were challenged by antitrust authorities in the U.S. and the EU as anticompetitive collusive behaviour between originators and generics delaying price competition through generic entry and harming consumers. Since settlement outcomes with large reverse payments can only occur in cases of potentially invalid patents ("weak patents"), this question is deeply linked to fundamental problems in the patent system. The controversies about patent settlements focus primarily on the role of reverse payments, i.e. whether they should be deemed as per se illegal, whether a (strong) presumption of illegality (with possibilities of rebuttals) should be applied or whether due to possible efficiency effects a rule of reason approach would be appropriate. Both in the US and the EU, so far no consensus could be reached among legal and economic scholars about the most appropriate antitrust solution.

In the U.S., the Federal Trade Commission (FTC) challenged such patent settlements with reverse payments in the pharmaceutical industry since 1999. The position of the FTC was and still is that patent settlements with reverse payments should be presumed as illegal with the possibility of a rebuttal by the parties, e.g. through litigation costs or other efficiencies (quick look rule).[2] After this policy of the FTC ran into much resistance in the U.S. courts (with contradictory decisions and reasonings; see Carrier 2012), the "Actavis" decision of the Supreme Court clarified that a large unexplained reverse payment can be a signal for the weakness of the patent and therefore the anticompetitiveness and illegality of such patent settlements. However, the Supreme Court also rejected the presumption of illegality approach of the FTC and wants the U.S. courts to apply a rule of reason approach, which also takes into account possible explanations for any value transfer from the originator to the generic firms.[3] In the EU, the European Commission (in its Pharmaceutical Sector Inquiry 2009, pp. 270) classified patent settlements and argued that the group of patent settlements with a restriction of entry and with a reverse value transfer requires closer competition policy scrutiny. This led the Commission to put this group of patent settlements under a special antitrust scrutiny in the newly adapted guidelines for the application of Article 101 (3) TFEU to Technology Transfer Agreements, and challenge and prohibit several patent settlements with reverse payments (e.g., in the case "Lundbeck"). Although the EU Commission acknowledges that settlements can have efficiency advantages like saving of litigation costs, time, and the resolution of uncertainty, it also emphasizes that society has an interest in removing wrongly granted patents to promote competition and innovation.[4]

How can the state of the academic discussion be briefly summarized? The large majority of scholars claim that patent settlements can be anticompetitive through delaying or impeding market entry and

[1] Janis/Hovenkamp/Lemley 2003, Bulow 2004, Hemphill 2006, Holman 2007, Carrier 2009, Brankin 2010, Edlin et al. 2013, Frank/Kerber 2013, Wang 2014.
[2] FTC 2002, p. vii; Case 570 U. S. ____ (2013) FTC v. Actavis, Inc. p. 20, Brankin 2010, p. 24, FTC 2010, p. 9.
[3] Case 570 U. S. ____ (2013) FTC v. Actavis, Edlin et al. 2013, Wang 2014.
[4] EC Guidelines on the Appl. Of Art 101 to TTA, pp. 44.

therefore restricting generic competition.[5] There is a nearly unanimous consensus among these scholars that the size of reverse payments is a crucial criterion for its anticompetitive effects. The main discussion refers to the question whether a presumption of illegality of patent settlements with reverse payments should be used, or whether a rule of reason approach should be applied. Although nobody denies the possibility of efficiency advantages of patent settlements,[6] there is a wide range of opinions whether a stronger or weaker presumption of illegality of patent settlements with reverse payments (with a smaller or larger set of possible rebuttals) or a full-blown rule of reason with a deep case-specific analysis should be recommended.[7] There also seems to be a broad consensus that, vice versa, patent settlements are not seen as being anticompetitive, if the parties only agree on future entry dates without a reverse net value transfer.[8]

There is only a limited number of articles about patent settlements in which explicit economic analyses can be found. Some articles address the problem of patent settlements in the pharmaceutical industry directly (either with economic models,[9] or at least with explicit economic reasonings[10]). But also other economic contributions about the broader problems of weak ("probabilistic") patents and the design of the patent system are relevant for this patent settlement problem.[11] This article intends to analyze critically what economic analyses have so far contributed to our knowledge about the effects of patent settlements in the pharmaceutical industry and the possible rules for their antitrust treatment. On one hand, this entails a critical analysis of these economic models themselves (and the claims made by them), and, on the other hand, also an analysis of the gaps in our knowledge and the open research questions. One crucial claim of this paper is that the problem of patent settlements can only be understood, if we analyze it not only from a narrow antitrust perspective but also take into account its deep interrelationship with the (economics of the) patent system.[12]

The paper is structured as follows: Section 2 will present the general problem of weak patents as part of the discussion about the problems of the patent system. Section 3 will focus on the relevant normative antitrust standard (consumer welfare) and distinguish three channels of possible effects of patent settlements on consumer welfare. Section 4 deals with the effects on consumers via price competition, i.e. that patent settlements with reverse payments might harm consumers through the delay of generic entry. However, relevant for consumer welfare are also the effects of patent settlements on innovation incentives (section 5) and the incentives for generics to challenge potentially invalid patents (section

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[5] Balto 2000, Crane 2002, Morse 2002, Janis/Hovenkamp/Lemley 2003, McDonald 2003, Bulow 2004, Leffler/Leffler 2004, Hemphill 2006, Ponsoldt/Ehrenclou 2006, Holman 2007, Leary 2007, Davis 2009, Carrier 2009, Brankin 2010, Gratz 2012, Edlin et al. 2013, Picht 2013, Carrier 2014b, Cotter 2014, Feldman 2014.

[6] Hemphill 2006, p. 121, Dickey/Orszag/Tyson 2010, p. 375, Brankin 2010, p. 23, Addanki/Butler 2014, p. 81.

[7] See, e.g., the "Actavis inference" as the most recent variant (Edlin et al. 2015).

[8] FTC 2010, p. 1, EC Guidelines on the Appl. Of Art 101 to TTA, pp.44, EC Pharmaceutical Sector Inquiry Final Report, p. 524 at para. 1573.

[9] Willig/Bigelow 2004, Elhauge/Krüger 2012, Gratz 2012, Addanki/Daskin 2009, Yu/ Chatterji 2011.

[10] Schildkraut 2004, Hemphill 2006, Carrier 2009, Davis 2009, Kobayashi et al. 2015, Edlin et al. 2015.

[11] Shapiro 2003, Lemley/Shapiro 2005, Farrell/Shapiro 2008, Encaoua/Lefouili 2009.

[12] Please note that this is a general paper about patent settlements in the pharmaceutical industry. Therefore it does not take into account the specific institutional conditions of different legal and regulatory systems, as, e.g., the Hatch-Waxman Act in the U.S. or the specific institutional characteristics in the EU. Therefore we also do not want to derive specific policy conclusions in that regard.

6). The final section 7 will summarize our results, identify gaps of research, and discuss policy conclusions.

2. The Background Problem: Weak Patents and Defects of the Design of the Patent System

The problem of patent settlements in the pharmaceutical industry stems from the fact that a large number of granted patents are found invalid in patent litigation, which gives patent holders large incentives to defend their weak patents through settlements with reverse payments to challenging generic firms. An important reason is that patent offices do not invest enough time and resources in patent examination (esp. in regard to "prior art") and therefore tend to grant too many patents which often would not survive a challenge in patent litigation ("weak patents"). Empirical studies show that litigated patents are found invalid in 50% (or more) of all cases (Lemley/Shapiro 2005, p. 76). This result could be interpreted as a defect of the patent system. However, Lemley (2001) argued from an economic perspective, that such a result might also be efficient, because it might not be worthwhile to make deep and costly examinations of all patent applications, because many of the granted patents turn out as not valuable (rationally ignorant patent offices). But both interpretations lead to the conclusion that it is necessary that the patent system has effective legal instruments for challenging and weeding out invalid patents. It is an open question in the patent literature, whether and to what extent the institutional design of the entire patent system (with all its rules about granting, opposing, and challenging patents in courts) leads to an efficient patent system or - as in the meantime most legal and economic scholars claim - that the existing patent systems are deeply flawed and suffer from serious problems (Shapiro 2004, pp. 1018, Hall/Harhoff 2004, pp.4).

An economic perspective on this problem of weak patents has led to the development of the concept of "probabilistic" patents or “partial property rights” which has played a major role in the patent settlement discussion.[13] The basic idea is simple: Whereas from a legal perspective a patent right is either valid or not, the economic value of a granted patent right before litigation depends also crucially on the expected probability of defending it in patent litigation. If this probability is, e.g., $\theta = 0.25$, then the expected value of the patent for the patent owner is much lower than the value of a fully defendable (iron-clad) patent right. This probability θ is used for defining the strength of a patent. This "probabilistic" character of a patent has been used in the patent settlement discussion in two different ways: Since the patent strength θ reflects the winning probabilities of the settling parties in patent litigation, it influences the ranges of the settlements (in regard to agreed entry dates and/or the size of reverse payments). In the economic models but also in argumentations of legal scholars, this has led to conclusions that a 25% chance of defending a patent against a challenging generic firm would lead to a settlement on an agreed entry date without reverse payment of 25% of the remaining patent duration (e.g. Elhauge/Krüger 2012, pp. 295). However, it can also be used for the analysis of the innovation incentives that such a probabilistic patent offers (e.g. how large are the incentives for an innovation that allows for a patent with a patent strength of 25%). In their seminal paper "How Strong are Weak Patents?" Farrell/Shapiro (2008, p. 1348) assume that innovation incentives for probabilistic patents are optimal, if the proportionality principle is fulfilled, i.e. that incentives for an innovation from a probabilistic patent are proportional to its patent strength, i.e. that the rents from a patent with $\theta = 0.5$

[13] See Ayres/Klemperer 1999, Shapiro 2003, Farrell/Shapiro 2008.

should be half of the rents of an iron-clad patent ($\theta = 1$) and twice the rents for a patent with $\theta = 0.25$. Farrell/Shapiro (2008) have suggested that profits from weak patents might be relatively too large in comparison to stronger patents, leading to a distortion of innovation incentives in favour of "innovations" that only with a small probability are true innovations that should be rewarded by patent protection (see below section 5).

It is well known that the challenging of potentially invalid patents can suffer from serious incentive problems. Since all patent systems rely on private litigation for challenging patents, the private incentives for challenging patents suffer from a public good problem, because the costs and risks of patent litigation is borne by the challenging firm, whereas the benefits of having eliminated an invalid patent right accrues to everybody.[14] This externality of challenging patents cannot only lead to too small incentives for challenging firms, but also implies that patent settlements between originator and generic firms can have negative (external) effects on third parties, because the settlement helps to maintain an unjustified exclusive right. Due to these third-party effects, the usual normative notion that private parties should be free how to settle their conflicts in private litigation is problematic in the case of patent litigation. Therefore rules for critically scrutinizing and limiting the scope of patent settlements are justified also from an economic perspective. However, this is not only a problem of patent settlements. Shapiro (2003) showed that patent owners can achieve the same result of defending their weak patents also through licensing agreements (with too low license fees), mergers, and patent pools leading him to the conclusion that all of these transactions should be put under antitrust scrutiny.[15]

3. Assessing Antitrust Rules for Patent Settlements: Normative Questions and the Distinction Between Three Groups of Effects

What is the correct normative criterion for assessing antitrust rules for patent settlements? Most influential and representing also the ex- or implicit opinions of many other scholars is the criterion that a patent settlement should not lead to a lower consumer welfare than it can be expected from litigation (Shapiro 2003, p. 396).[16] According to him, "... consumers have a 'property right' to the level of competition that would have prevailed, on average, had the two parties litigated the patent dispute to a resolution in the courts. So long as the consumers' rights to this level of competition/benefits are respected, the two parties are permitted to negotiate more profitable arrangements that they each prefer to litigation" (ibid.).[17] In line with the "probabilistic" perspective on patents, this also implies that “patent holders are not entitled to the same level of profits that would result from an ironclad patent covering the same patent claims" (ibid.).

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[14] See Farrell/Merges 2004, pp. 952, Hemphill 2006, pp. 150. This is the reason why in the U.S. the Hatch-Waxman Act intended to increase the incentives of generic firms by giving the first challenging firm a 180-days-exclusivity right in regard to market access (in comparison to other generic firms). However, the 180-day mechanism is also critically discussed, since it might open opportunities for making collusive settlement agreements with the first filer while others are excluded (Janis/Hovenkamp/Lemley 2003, p. 1755, Hemphill 2006, p. 108, Carrier 2009, pp. 61).

[15] Closely related to this problem is also the discussion about the antitrust assessment of "non-challenge clauses" in licensing agreements (Janis/Hovenkamp/Lemley 2003, pp. 1721).

[16] E.g. Blair/Cotter 2002, Janis/Hovenkamp/Lemley 2003, Schildkraut 2004, Elhauge/Krüger 2012, Gratz 2012.

[17] However, this is not the same as the "less-restrictive alternative" standard, which is also used in Art. 101 (3) of the European competition rules.

The manifold effects of antitrust rules for patent settlements can affect the welfare of consumers through three different channels:

(1) The discussion so far focussed mainly on the (static) price effects through the potential delay of competition by generic entry. The question here usually is whether patent settlements lead to such a late entry of generics that the benefits of future lower prices through generic competition for the consumers are less than what could be expected in the case of patent litigation.

(2) Antitrust rules on patent settlements can also influence the innovation incentives, i.e. the question is whether more restrictive rules for defending patents through reverse payments might lead to lower innovation incentives for originator firms (dynamic efficiency) and therefore also harm consumers in the future.

(3) The third channel for effects on consumer welfare are the effects of antitrust rules on patent settlements for the incentives of generics to challenge weak patents. If patent settlements, for example through reverse payments, can also increase the incentives for challenging potentially invalid patents, then a lower number of monopolistic market positions are protected by unjustified patents until the expiration date, leading to higher consumer welfare through more generic competition.

Should the last two groups of effects be relevant for an assessment of patent settlements from an antitrust perspective? The argument might be made that they relate both to effects on innovation and the patent system, and should therefore not be a concern of competition law. However, the problem is more complex: First, although the main discussion focusses on the static price effects, also the other effects have been discussed and mentioned as relevant both from legal and economic scholars in the antitrust discussion about patent settlements. In the EC Guidelines on Technology Transfer Agreements the "general public interest to remove invalid intellectual property rights as an unmerited barrier to innovation and economic activity"[18] was explicitly mentioned. In the U.S., it is the Hatch-Waxman Act which explicitly intended to increase the incentives of generic firms for challenging invalid patents of originator firms. Therefore the second and third group of effects have always been present in this discussion. Secondly, from an economic perspective, the criterion of using the consumer welfare in the case of litigation as normative standard would also entail the effects on innovation incentives and incentives to challenge invalid patents. However, this touches the difficult and hotly disputed issue of the proper delineation between problems that should be dealt with in competition law or in patent law. We will come back to this discussion at the end of this paper.

4. Effects on Consumer Welfare via Prices

Nearly the entire literature on patent settlements in the pharmaceutical industry has focussed on the effects that settlements with or without reverse payments might have on the entry date of generics and therefore on the question when generic competition does lead to lower prices for drugs. Since there is a broad consensus that settlements should be preferred to litigation due to litigation costs, the crucial question concerns the antitrust limits that should be set for settlements in order to avoid negative effects for consumers via prices. In the following, we summarize and analyze the results of this discussion from an economic perspective. It is surprising that - despite all the controversies - most of the

[18] EC Guidelines on the Appl. Of Art 101 to TTA, p. 44 at para. 235.

contributions both from economic and legal scholars use roughly the same basic economic model, either explicitly or implicitly.[19] Therefore it is useful to present briefly the assumptions, reasonings, and conclusions of this basic model.

The basic patent settlement model

It is assumed that an originator firm A has a patent which allows for annual monopoly profits M_A for the remaining patent duration T, and there is only one firm B that can challenge the patent. If this generic firm B would enter the market at entry date E, both firms have annual duopoly profits D_A and D_B.[20] Since duopoly prices are lower than monopoly prices, the annual welfare of consumers under duopoly (W_D) is larger than under monopoly (W_M). If we assume that the true patent strength (probability of defending successfully the patent in litigation) is θ, then the consumers can expect with probability θ a lower consumer welfare due to high monopoly prices and with probability 1 - θ a higher consumer welfare due to lower duopoly prices after revocation of the patent.[21] According to the normative criterion of Shapiro the consumer welfare in the settlement case should not be smaller than in the litigation case ($W_S \geq W_L$). If in the settlement both parties have agreed on an entry date E (e.g., in 2 years), the consumer welfare in the case of settlements is $W_S = E\ W_M + (T - E)\ W_D$, i.e. for two years consumers suffer from the low consumer welfare under monopoly prices before their welfare is increased through lower duopoly prices for the rest of the patent duration. This implies that under these assumptions the normative criterion is fulfilled, if the entry date of the generic is not later than the strength of the patent θ multiplied with the remaining patent duration T (i.e., $E \leq \theta\ T$ (for the following analysis, we define: $E^* = \theta\ T$). For example, this would mean that a patent strength of 20% would translate into an entry date after 20% of the remaining patent duration T, i.e. if T = 10 years, i.e. generic entry should be not later than in two years.

What are the results of a patent settlement between both firms? From the law and economics of settlements we know that the settlement range between both firms is determined by the outside options and these are the expected values of litigation of both parties. In this simple version of the model we assume that both firms know the true patent strength θ and have litigation costs c_A and c_B.[22] In the settlement the parties can agree on an entry date E and a reverse payment R that is paid by the patent holder to the generic firm. What settlement would be optimal for both firms, if there were no antitrust limits? It can easily be shown that joint profit maximization would lead to a settlement, in which both firms agree to delay market entry of the generic firm until the expiration of the patent (i.e. $E > E^* = \theta\ T$). The joint profits would be identical to the monopoly profits of an iron-clad patent with a patent strength θ = 1. The generic would need to get a reverse payment which is not lower than its expected value of litigation. The consumers would be worse off compared to litigation, and the loss of consumer

[19] See e.g. Dickey/Orszag/Tyson 2010, Elhauge/Krüger 2012, Yu/Chatterji 2011, Gratz 2012, Edlin et al. 2013.

[20] The sum of the two duopoly profits is smaller than the monopoly profit ($D_A + D_B < M_A$).

[21] Therefore the expected consumer welfare in case of litigation is: $W_L = \theta\ T\ W_M + (1 - \theta)\ T\ W_D$. Please note that the consumer welfare in the litigation solution depends on the true patent strength θ and not on the subjective estimations of the firms A and B about the strength of the patent, i.e. θ_A and θ_B. This is often overlooked in the literature.

[22] Then the expected value of litigation is for A: $V_{LA} = \theta\ T\ M_A + (1 - \theta)\ (T\ D_A) - c_A$; and for B: $V_{LB} = (1 - \theta)\ (T\ D_B) - c_B$.

welfare through such patent settlements increases with the weakness of the patents.[23] If the firms are not allowed to maximize their joint profits in the settlement due to antitrust limits, we can analyze the relation between the agreed entry date E and the reverse payment R. The earliest entry date that the originator would accept (E_{min}) as well as the latest entry date acceptable for the generic (E_{max}) depends on the expected monopoly and duopoly profits, the litigation costs, and the reverse payment. Most influential for the entire discussion is the result of the model that in the case of the absence of reverse payments (R = 0), an agreed entry date can be expected which is very close to the normatively correct entry date $E^* = \theta T$. And: The higher the reverse payment R, the later is the generic entry and therefore the welfare losses for consumers.[24]

From this basic model several conclusions can be derived that have been very influential in the policy discussion:

(1) The normative criterion that patent settlements should not harm consumers compared to patent litigation translates into the criterion that generic entry should not be later than $E^* = \theta T$, i.e. the agreed time of generic entry should be strictly proportional to patent strength.

(2) If there are no reverse payments, then the bargaining would lead to a settlement range around this optimal entry date $E^* = \theta T$. As soon as the reverse payment R is larger than the litigation costs of the originator (i.e., $R > c_A$), the agreed entry date E is later than the optimal entry date E^* and therefore anticompetitive.

(3) Reverse payments are a very effective instrument for restricting price competition through generic entry. Increasing reverse payments leads directly to later entry dates and higher joint profits and higher welfare losses for consumers compared to patent litigation.

(4) Without antitrust limits for patent settlements, the settling parties would agree on an entry date at the end of patent duration T, i.e. weak patents would lead to the same profits and consumer welfare as iron-clad patents with a patent strength $\theta = 1$.

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[23] The value of the settlement solution would be for firm A: $V_{SA} = E\ M_A + (T - E)\ D_A - R$; and for firm B: $V_{SB} = (T - E)\ D_B + R$. If both firms maximize their joint profits for finding the most profitable settlement solution, their joint profit would be: $V_{SAB} = V_{SA} + V_{SB} = E\ M_A + (T - E)\ (D_A + D_B)$. Since $D_A + D_B < M_A$, it is optimal for both of them to agree delaying the generic market entry until the expiration of the patent, i.e. $E = T$ (with $V_{SAB} = T\ M_A$). For agreeing to this settlement the generic firm would at least need a reverse payment that equals its value of litigation: $R_{min} = V_{LB} = (1 - \theta)\ (T\ D_B) - c_B$. Vice versa, the maximal reverse payment that the patent holder A would be willing to pay equals its monopoly profits minus its value of litigation: $R_{max} = T\ M_A - V_{LA} = (1 - \theta)\ T\ (M_A - D_A) + c_A$. Therefore the range for the reverse payment R would be: $(1 - \theta)\ (T\ D_B) - c_B \leq R \leq (1 - \theta)\ T\ (M_A - D_A) + c_A$. Economically, the benefits of such a settlement for both parties consist of the additional profits (because: $M_A > D_A + D_B$) plus the saved litigation costs c_A and c_B. The consumer welfare in this case, $W_S = T\ W_M$, is identical with the case that the patent holder can get monopoly profits for the entire duration of its patent. Therefore it is considerably smaller than under litigation: $W_S - W_L = T\ W_M - [\theta\ T\ W_M + (1 - \theta)\ T\ W_D] = (1 - \theta)\ T\ (W_M - W_D) < 0$.

[24] The earliest entry date, E_{min}, that the patent holder would accept is $E_{min} = \theta\ T - c_A / (M_A - D_A) + R / (M_A - D_A)$, and the latest acceptable entry date for firm B is $E_{max} = \theta\ T + c_B / D_B + R / D_B$. We see that increasing the reverse payments R shifts the settlement range in the direction of later entry dates, which would increase profits and reduce consumer welfare. If, however, there are no reverse payments (R = 0), we get a settlement range $\theta\ T - c_A / (M_A - D_A) \leq E \leq \theta\ T + c_B / D_B$ around the optimal entry date $E^* = \theta\ T$, and the range on both sides depends only on the litigation costs of both parties (divided by the profit changes through the entry). If, in addition to that, there would be no litigation costs ($c_A = c_B = 0$), then the agreed entry date in the settlement would exactly equal the normatively correct one: $E = E^* = \theta\ T$.

(5) This model also suggests that patent settlements without reverse payments are not anticompetitive, because they usually lead to the correct entry date.[25]

From these results, it can easily be understood why antitrust scholars are so concerned about reverse payments, and why antitrust rules were proposed that prohibit reverse payments (beyond litigation costs) or recommend at least a strong presumption of their illegality. However, the decisive question from an economic perspective is whether these results still hold, if we take into account that the conditions on pharmaceutical markets and in settlement processes are in reality much more complex than represented by the very simple assumptions of this model. This is the starting-point of primarily economic papers that can show that under more realistic assumptions these simple conclusions do not hold and therefore also patent settlements with reverse payments (beyond litigation costs) can be efficiency-enhancing and do not harm consumers, supporting the calls for a rule of reason approach (esp. Willig/Bigelow 2004). In the following, we cannot discuss all these specific reasonings, but provide a broader assessment of the consequences of relaxing the strict assumptions of this model.[26]

Implications of more realistic assumptions

One example are knowledge assumptions about patent strength. Since nearly the entire literature assumes that the true patent strength θ is unknown, it cannot be assumed as in the basic model that the firms know the true patent strength or that they have the same subjective estimates about the patent strength. A number of papers have focussed on the analysis of settlement outcomes, if the patent holder and the entrant have different estimates about patent strength (optimistic/pessimistic).[27] Depending on the specific assumptions the settlement ranges in these cases can get broader (and making settlement easier) or smaller. It can even get negative, which despite the saving of litigation costs might make a settlement impossible without reverse payments.[28] The other possibility is that both parties might generally over - or underestimate the patent strength. If the parties overestimate the patent strength (i.e., $\theta_A = \theta_B > \theta$), then even without reverse payments the agreed entry date will be later than the normatively optimal one ($E > E^*$), rendering this patent settlement anticompetitive. Vice versa, in the case of an underestimation of the patent strength ($\theta_A = \theta_B < \theta$), the agreed entry date (with $R = 0$) will be earlier than the optimal one ($E < E^*$), which would allow positive reverse payments (beyond litigation costs) without making the patent settlement anticompetitive.

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[25] E.g. Shapiro 2003, Dickey/Orszag/Tyson 2010, pp. 379.

[26] For caveats in regard to the conclusions from the basic settlement model, if more realistic assumptions are considered, see already Shapiro (2003, 410). He mentioned explicitly multiple challengers, asymmetric information, signaling, risk aversion, and also the existence of a portfolio of patents as unresolved topics.

[27] Willig/Bigelow 2004, pp. 672, Davis 2009, p. 292, Schildkraut 2004, pp. 1064.

[28] Willig/Bigelow (2004, pp. 672) analyzed such a case. They assume that the incumbent patent holder knows the true patent strength and the entrant is overoptimistic, i.e., assumes a too low patent strength ($\theta = \theta_A > \theta_B$). Willig/Bigelow are right that this is a case, in which the wrong estimate of the entrant makes a procompetitive settlement without a reverse payment impossible. However, if a competition authority or court does not know the true patent strength, then this case cannot be distinguished from another case, in which the entrant knows the true patent strength and the patent holder is over-optimistic ($\theta_A > \theta_B = \theta$), and in which a settlement with reverse payment would clearly lead to a too late entry and therefore would be anticompetitive.

Similar results can be derived, if one or both firms make wrong predictions about the future market conditions (market demand, new substitutes, market shares between brand name and generic products, co-payment rules of insurances etc.), and therefore their expected future monopoly and duopoly profits. For example, in the case of underestimation of the duopoly profits D_B and no reverse payments (R = 0), a generic firm would accept later entry, which might lead to an anticompetitive patent settlement (despite the absence of reverse payments).[29] Please note that in the basic model it was assumed that both firms A and B have the same and correct predictions about future market conditions, which are very unrealistic assumptions. Any kind of wrong and/or different predictions and other information asymmetries will lead to different settlement outcomes in respect to agreed entry, which might be far from the optimal entry date (as derived in the basic model). One of these cases was modelled by Willig/ Bigelow (2004, pp. 667). They can show that in a case of asymmetric information about the value of a patent a procompetitive settlement is only possible with a reverse payment.

Settlement outcomes can also change due to other factors. In the basic model it was assumed that both parties are risk-neutral. In the case of risk-averse originators or entrants settlement economics shows that the settlement ranges and therefore also the agreed entry dates and/or reverse payments change (Willig/Bigelow 2004, p. 666). There is a discussion in the literature that originator firms might be particularly risk-averse in respect to their probabilistic patents, implying that they would accept early generic entry despite making reverse payments.[30] So far not analyzed in economic models about patent settlements are strategic considerations of originator or generic firms. Since both the originator and often also the generic firms are usually large firms which are active in many markets and producing and selling a number of products and have a portfolio of patents, there might be other relevant strategic considerations for the decision about litigation or settlement in regard to a specific patent than only the future monopoly or duopoly profits of this one product. This also can change settlement ranges and therefore influence agreed entry dates and reverse payments.[31] Analyzing the effects of strategic considerations, especially in multi-product and/or multi-market contexts, would be an interesting field of further research.

The multiple challenger/entrant problem

A particular problem of all economic models about the patent settlement outcomes is that - contrary to the assumption in the basic model - more than one generic firms can challenge and enter the market. If originator firms are aware of multiple potential generic entrants, then they have to consider in their settlements with the first challenger that they might have to make several settlements for defending their weak patents, as well as the generic has to take into account the expected entry of more generic firms. This will change both the upper and lower limits of the settlement ranges, and also leads to the consequence that the patent settlements with several generics are not independent from each other anymore. This multiple challenger/ entrant problem, which is also directly linked to the public good

[29] For R = 0: $E_{max} = \theta\ T + c_B / D_B$; therefore an underestimation of the profits D_B leads to a higher upper bound of the settlement range E_{max}.
[30] Schildkraut (2004, pp. 1061); for explaining risk aversion of firms through risk aversion of managers see Willig/Bigelow (2004, p. 666, fn. 10) and the critique in Elhauge/Krüger (2012, p. 312).
[31] Strategic considerations and patent portfolios are mentioned in Shapiro (2003, 410) and Davis (2009, p. 292).

problem of challenging weak patents, has not been analyzed so far. It is also linked to the problem that generally competition among generic firms in regard to challenging and market entry has not been analyzed sufficiently.[32] [33] Therefore the implications of the existence of multiple challengers on the assessment of patent settlements are unclear, although such a situation seems to be empirically more relevant than assuming only one potential entrant (Grabowski/Kyle 2007, pp. 500).

Conclusions

If we take into account that in reality the assumptions of the basic model are not fulfilled (due to information problems about patent strength and future market conditions, risk aversion, strategic considerations, and the existence of multiple potential entrants), then we can expect that in most cases the patent settlement outcome will not correspond to the outcome of patent litigation (even in the case of no reverse payments).[34] Depending on the specific conditions the agreed entry dates might be earlier or later, and therefore also consumer welfare might be higher or lower.[35] Especially problematic is that in regard to important aspects we so far do not have enough economic research.

This leads to the following preliminary conclusions:

(1) There will be a number of patent settlements without reverse payments, which harm consumers in comparison to litigation and are therefore anticompetitive, because the agreed entry date is later than the optimal one ($E > E^*$). Therefore the prohibition of reverse payments does not ensure that patent settlements are not anticompetitive.[36]

(2) There will also be a number of patent settlements with a certain amount of reverse payments (even beyond litigation costs), which will not harm the consumers, i.e. the entry date will be not later than the optimal one ($E \leq E^*$). In a part of these cases, these reverse payments might be necessary for achieving litigation cost-saving settlements.

(3) Although both results imply that the observed size (or absence) of reverse payments is not a very reliable indicator for assessing the (il)legality of the patent settlements, economists would agree that even under more realistic conditions than in the basic model reverse payments can be a very effective and easily applicable instrument for restricting competition between originators and generic firms. Therefore it is justified that (high) reverse payments should raise (serious) antitrust concerns.

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[32] Willig/Bigelow's (2004, pp. 673) analysis of an additional entrant is not a case of an additional challenger, because the entrant offers a substitute product (which does not infringe the patent). Also Edlin et al. (2015, pp. 19-28) do not analyze the multiple challenger problem. Their analysis refers to the consequences of more price competition, if after the 180 days exclusivity period for the first generic entry (in the U.S. Hatch-Waxman framework) several additional entrants instead of only one enter. Only in the model of Gratz (2012) a second generic entrant with a second settlement is included but without addressing the multiple challenger problem.

[33] In the U.S., this problem is deeply influenced by the Hatch-Waxman Act due to the 180 days market exclusivity for the first entrant, which both protects the first generic against the competition of other generics but also protects the originator against more challenges from other generics (FTC 2002, p. vi).

[34] Especially Davis (2009) also emphasized the range of possible outcomes in settlement processes due to a number of "imperfections" of the settlement process.

[35] This also implies that the settlement results (e.g., the agreed entry dates) do not allow to make reliable conclusions about the true patent strength as it is suggested by the basic model.

[36] See also Elhauge/Krüger (2012) who even try to show that on average patent settlements without reverse payments are anticompetitive.

(4) Another additional problem of using the size of reverse payments as important criterion is that originator and generic firms can hide the (size of) reverse payments through complex package deals (e.g., licensing agreements, deliveries of ingredients), which require difficult and error-prone evaluations for determining the correct net value transfer.[37]

5. Effects on Consumer Welfare via Innovation Incentives

In the patent settlement discussion the question was asked whether restrictive antitrust rules on patent settlements with reverse payments might have negative effects on innovation incentives for the originators and therefore also harm consumers in the long run through fewer development of new drugs.[38] Since it is a well-established insight in the economics of patents that innovation incentives through patents should not be too small but also not too large (leading to the notion of optimal length and breadth of patents),[39] it is clear that it cannot simply be argued that the fact that the prohibition of reverse payments would lead to lower profits for the originator firms would lead to the consequence that the innovation incentives are smaller than optimal. Since innovation incentives can also be too large, a much deeper economic analysis is necessary.

In regard to the economic contributions to the patent settlement problem in the pharmaceutical industry, Elhauge/Krüger (2012) explicitly presented a model, in which they analyze both static price effects and innovation incentive effects. In regard to patent settlements they prefer a strong presumption against patent settlements with reverse payments (that are larger than litigation costs of the originator) with only a few possibilities of rebuttals. They want to show that such a rule would not lead to a trade off between static price effects on consumers and effects on innovation incentives. Whereas their analysis of price effects uses (a variant of) the basic model (as presented in section 4), it is their analysis of the effects of patent settlements on innovation incentives which is relevant here. Starting from the above-mentioned insight that both a too long and a too short exclusion period through patents is not optimal from an innovation economics perspective (ibid, pp. 293), they apply an innovation-incentive perspective on the concept of probabilistic patents. They explicitly assume that a patent with a patent strength of $\theta = 0.25$ should from an innovation incentive perspective be equal to an ironclad patent of 5 years (25% of the patent duration of 20 years), i.e. the innovation incentives that should be granted to an innovation by a probabilistic patent should be proportional to the patent strength (proportionality principle, Farrell/Shapiro 2008) and can be translated into a share of the patent duration. Although a lot of assumptions have to be made for defending such a linear transformation in years of patent duration,[40] the basic idea is in line with such an innovation incentive interpretation of probabilistic patents.

However, in our view, in their next step Elhauge/Krüger (2012) make a serious mistake. From an innovation economics perspective, the optimal entry date in a patent settlement needs to be calculated in

[37] In regard to the problem of side deals, see Hemphill (2009). Very interesting is his proposal of a presumption of the problematic character of a patent settlement, if it is embedded into a package of side-deals, whose existence is unusual in the absence of a patent settlement.
[38] Crane 2002, pp. 760, Shapiro 2003, p. 396, Willig/Bigelow 2004, pp. 656, fn. 3.
[39] See e.g. Gilbert/Shapiro 1990.
[40] This would assume constant rents from the innovation over time and the absence of the need of discounting future revenues.

regard to the entire patent duration of 20 years, i.e. a patent with a patent strength of 25% should lead to a generic entry after 5 years of the entire patent duration. Instead Elhauge/Krüger (2012) erroneously define their normative benchmark for the optimal innovation incentives perspective as a percentage of the remaining (!) patent duration at the time of the settlement. This, however, ignores that the originator already earned monopoly profits from the date of granting the patent until the date of the patent challenge and settlement. If, for example, a patent with a patent strength of 25% is challenged after five years of its patent duration, then the originator firm has already reaped all the necessary rewards for its innovation (according to the innovation incentive interpretation of probabilistic patents) and any more delay of generic entry would lead to too high innovation incentives. Therefore their normative benchmark about optimal innovation incentives for patent settlements is flawed, because it would allow for too large innovation incentives (except the extreme case that a patent is challenged right at the beginning of the patent duration).[41] Due to this mistake at the beginning of their otherwise convincing analysis, the conclusions of Elhauge/Krüger (2012) do not hold that there might be no conflict between dynamic and static effects on consumers under their proposed rule of presumptive illegality of patent settlements.

Based upon an adaptation of the standard optimal patent term model Woodcock (2016a) analyzes whether the delay of generic entry through patent settlements would increase consumer welfare through higher innovation incentives. After having calibrated the model with U.S. drug market data, he finds that settlements delaying entry for more than 15 months will harm consumers. Therefore, he is also sceptical that patent settlements will increase consumer welfare via more innovation incentives, even in cases without reverse payments.[42]

How can the economic knowledge about the innovation incentive effects of patent settlements be summarized?

(1) Most important is that much more research is needed, before reliable answers can be given. Except Elhauge/Krüger (2012) and Woodcock (2016) all other contributions from an economic perspective did not analyze and take into account the innovation incentive effects at all.

(2) From the analysis of Elhauge/Krüger (2012) one specific thesis can be suggested. Since their results are systematically biased into one direction, it might be suggested from our critique above, that the agreed entry dates in patent settlements without reverse payments might be leading to too large innovation incentives for the originator firms. This analysis also shows that from an innovation economics perspective the date of the challenge and settlement within the lifetime of the patent is getting important, which so far has not played any role in the antitrust discussion about patent settlements. This would imply that also patent settlements without reverse payments might be anti-

[41] If D is the number of years the patent holder could reap monopoly profits before the settlement (with D + T = 20), then the optimal entry date from an innovation incentive perspective under the proportionality principle would be $E^* = \theta\, 20 - D$, which is always smaller than the agreed entry date in a settlement, $E = D + \theta\, T$ (as long as $D > 0$) and can also be negative (if $D > \theta\, 20$). However, there is one specific effect, especially in regard to pharmaceutical products, that has to be considered additionally: If the originator firms can sell their products only after a certain period of time (due to clinical tests and getting the market approval), then this period would also have to be considered.

[42] See also Woodcock (2016b). Leffler/Leffler (2004) are also critical about too large innovation incentives and argue that patent settlements increase expected profits of patent holders compared to litigation by preventing patent challenges. If patent challenges (and settlements) are part of the institutional design of the patent system this would lead to innovation incentives larger than granted by the patent (pp. 38).

competitive due to too large innovation incentives. Therefore trade offs between the static price effects and the dynamic innovation incentive effects cannot be excluded, and they might be much more severe for (a) patents that are challenged late in their patent life and/or (b) for weaker patents.

(3) This last point is directly linked to the important general analysis of Farrell/Shapiro (2008). In their model they show that under certain conditions weak patents might lead to disproportionately too high innovation incentives compared to innovations that allow for patents with a higher patent strength.[43] This might lead to too large incentives for investing in pseudo or trivial innovation activities and therefore discourage the search for true innovations. Also in regard to this problem much more research is needed.

(4) Although the results of these analyses are very preliminary and should be viewed with cautiousness, it is remarkable that all of them tend to lead to the conclusion that antitrust authorities and courts perhaps should not be too worried about curbing too much innovation incentives, if they pursue a restrictive approach to reverse payments and patent settlements in general.

6. Effects on Consumer Welfare via Incentives for Challenging Patents

In the patent settlement discussion a number of authors raised the question whether prohibiting or limiting reverse payments would reduce the incentives of generics for challenging potentially invalid patents, e.g. Chief Justice Roberts in his dissenting opinion in the Actavis Supreme Court decision.[44] Since in the EU guidelines for licensing agreements also the relevance of removing invalid patents is mentioned in regard to the assessment of patent settlements, the incentives for challenging weak patents are also important for the EU Commission. In section 2 we saw that these challenging incentives would not be so important, if the patent offices would not grant so many weak patents and if the patent system would not rely so much on private litigation for weeding out invalid patents. So far most of the economic contributions dealing with patent settlements did not take into account the effects on the incentives to challenge weak patents. Only the models of Gratz (2012) and Böhme/ Frank/ Kerber (2016) offer integrated analyses of the static price and challenging incentive effects of patent settlements.

Challenging weak patents and weeding out potentially invalid patents through patent opposition and patent litigation requires resources that in a system of private litigation have to be borne by private parties. Since the consumers are the victims of unjustified monopoly positions of originator firms in the case of invalid but unchallenged patents, the generic firms can be viewed as agents of the consumers who challenge these patents and drive down prices through generic entry. Since generics need profits that also cover the challenging costs, it is the consumers who ultimately have to bear the costs of incentivizing generics for challenging patents. In the U.S., the solution of the Hatch-Waxman Act of granting the first entrant a 180 days exclusivity period for solving the public good problem, can be interpreted in that way: Consumers pay with higher prices due to less generic competition during the

[43] The reason is that downstream firm's incentives to challenge probabilistic patents could be smaller than optimal since other downstream firms as well as consumers could free-ride on a challenge (Farrell/Shapiro 2008, p. 1349). A follow-up paper of Encaoua/Lefouili (2009) confirmed these results but questioned their robustness under different settings.

[44] Case 570 U. S. ____ (2013) FTC v. Actavis, Roberts, C.J. dissenting pp.17; see also Dickey et al. 2010, p. 399, Gratz 2012, p.15.

180 days exclusivity period for the challenging incentives for generics. This idea of a trade off for the consumers between lower prices through earlier generic entry and higher challenging incentives for generics can also be applied directly to the antitrust treatment of patent settlements. The basic idea is that it might be worthwhile for the consumers if competition law would allow patent settlements with a later generic entry date than the optimal entry date E* (derived in section 4 when only price effects were considered). Since the generics would participate in the higher joint profits through the delay of generic entry (which might require reverse payments), their incentives for challenging more weak patents increase. This would lead to more generic entry and lower prices for the consumers in regard to other pharmaceuticals whose protection through weak patents would otherwise remain unchallenged. From that perspective the question can be raised whether and to what extent competition authorities and courts should perhaps be more lenient with pay-for-delay settlements and ensuing reverse payments and allow for an additional period of delay.

In their model Böhme/Frank/Kerber (2016) analyze this question directly by asking for the optimal additional delay that would maximize consumer welfare through taking into account both the negative effects through the additional delay and the positive effects on consumer welfare through challenging more patents. The structure of their model is partly based upon the model of Gratz (2012), who was the first to offer an integrated analysis of price and challenging incentive effects. In both models there are originator firms with patents of different strengths ($0 \leq \theta \leq 1$) and two generic firms that can challenge patents (with fixed challenging costs) and enter sequentially the market at different future dates. A later agreed entry date in the ensuing settlements leads to larger joint profits and therefore to more challenging incentives for generics in both papers. However, Gratz (2012) assumes that the courts unintendedly accept patent settlements with later generic entry, because under a rule of reason approach she assumes that the court would make errors due to information problems. Therefore her positive effect on challenging incentives is caused by judicial errors due to the application of a rule of reason approach.[45] Instead Böhme/Frank/Kerber (2016) treat the additional delay in their model as a policy parameter, which competition authorities and courts can intentionally take into account in their antitrust assessment of patent settlements (with agreed entry dates and reverse payments). They can show that if the challenging costs are not too low, such a delay would increase under relatively general conditions the welfare of consumers. The optimal additional delay of entry increases with the size of challenging costs, the intensity of competition (after generic market entry), and the length of the time between the first and second generic entry. However, their model shows that - depending on parameter constellations - this policy parameter can also be negative. This would mean that under the litigation solution the challenging incentives are already too high and therefore consumer welfare could be increased by earlier generic entry than expected under litigation. In this case also patent settlement without reverse payments would lead to a too long collusion period. Since originators and generics have always the right to litigate as outside option, it would not be possible to force the parties through antitrust limits of patent settlements to agree on an earlier generic entry that would maximize consumer welfare. Therefore their model shows that it depends on parameter constellations whether increasing challenging incentives can be an argument for allowing an additional entry delay (and therefore might justify reverse payments).

[45] The analysis of Gratz (2012) about the superiority of a rule of reason is not convincing, because (1) it is unclear why the effects from judicial errors in her model only lead to the acceptance of more anticompetitive patent settlements and not also to the rejection of more procompetitive patent settlements, and (2) usually a rule of reason leads to less error costs and not more as in her model.

The policy conclusions that can be drawn from specific economic models are always limited. We would not recommend that based upon the results of such a model competition authorities or the courts should allow for a specific additional period of collusion between originators and generics (and accept also the additional reverse payments). However, we would claim that the models show the existence of such a trade off, and that scholars who were concerned that a prohibition of reverse payments might lead to fewer incentives for challenges by generics might have some support in economic analysis.[46] However, much more research is necessary for clarifying further the link between the antitrust rules about patent settlements (with or without reverse payments) and the incentives for challenging patents. What is missing in the analysis of these models is the integration of the public good problem. Another so far neglected question refers to the problem of competition between generic firms in regard to the challenge of weak patents.

7. What Can We Learn From Economics? Insights, Open Questions, and Policy Conclusions

In the sections 4 to 6 we have analyzed what we know from economics how antitrust rules about patent settlements might influence the welfare of consumers of pharmaceuticals and where there are still significant gaps in research. In regard to the effects via prices, a basic settlement model with simplified assumptions can show that the agreed date of generic entry in patent settlements without reverse payments would lead to settlement outcomes whose consumer welfare implications are close to those of the outcome of litigation. However, economists also would agree that in reality the bargaining situations between originator and generic firms are much more complex and might suffer from a number of imperfections not considered in this basic model. Particularly information problems in regard to patent strength and future market conditions as well as risk aversion, strategic considerations and the implications of multiple generic challengers and competition among generic entrants will lead to settlement outcomes which can be far away from the normatively optimal entry dates. Only a small part of these problems have been analyzed so far (e.g. Willig/Bigelow 2004, Elhauge/Krüger 2012). However, it seems clear that these deviations can lead into both directions, i.e. they can render patent settlements without reverse payments anticompetitive as well as allow to some extent reverse payments without harming consumers. The latter can be the result of explicit efficiencies (as, e.g., saving litigation costs) but can also be the result of the "imperfections" of the bargaining situations in which efficiency-enhancing settlements would fail without the possibility of reverse payments.

The gaps in research are even larger in regard to the other two channels of effects, i.e. innovation incentives and incentives to challenge patents. Particularly problematic is the lacking research about innovation incentives. Although the analysis of innovation incentives in Elhauge/ Krüger (2012) suffers from a serious flaw, a further analysis based on their results as well as the study of Woodcock (2016) provide preliminary hints that patent settlements without reverse payments might lead to too large innovation incentives, esp. in the case of weak patents and in case of settlements in the later stages of the life of patents. More research about this problem can also be linked to the contribution of Farrell/Shapiro (2008) with their analysis whether weak patents might lead to disproportionately large innovation incentives. Also the problem of challenging incentives still lacks a lot of research. Gratz

[46] See e.g. Dickey/Orszag/Tyson 2010, p. 399.

(2012) and Böhme/Frank/Kerber (2016) can show that there might be a trade off between promoting a faster generic entry by prohibiting pay-for-delay patent settlements and increasing the incentives for challenging patents through generics. This leads Böhme/Frank/Kerber (2016) to analyze this trade off and ask for the determinants of an optimal additional delay of generic entry for increasing challenging incentives. However, many other aspects of the challenging incentive problem have not been taken into account in patent settlement models.

What can we learn from these economic insights in regard to the antitrust rules for patent settlements in the pharmaceutical industry? First, we have to consider that there might be trade offs between all three groups of effects (price, innovation, and challenging effects) on consumer welfare. Whereas the first preliminary results of the analysis of challenging incentives might give some support for allowing longer delays, the effects on innovation incentives might lead to the opposite result. These results lead to a further relativization of the results of the basic model in section 4 and its main conclusion that patent settlements without reverse payments would lead to an optimal agreed generic entry.

Does this result lead to the recommendation of a rule of reason approach instead of a presumption of illegality of patent settlements with reverse payments, because it would allow the analysis and consideration of all anticompetitive and efficiency effects under the circumstances of the specific case? From a law and economics perspective, this is not clear at all, because such a claim would require an error-cost analysis, which would make a comparative analysis of the different regulatory options in regard to the size of decision errors (false positives, false negatives) and direct and indirect regulation costs:[47] Would a full-blown rule of reason, a per se prohibition of patent settlements with reverse payments, a presumption of illegality (with a limited number of options for rebuttals), or another form of structured rule of reason lead on average to a minimization of the sum of regulatory costs and welfare costs of decision errors and therefore to higher welfare for the consumers? Although a number of authors have mentioned and partly used arguments from an error-cost perspective,[48] so far only Davis (2009) tried to analyze the problem of patent settlements in a systematic way from an error-cost framework by assessing error and transaction costs. In regard to his analysis, which leads him to the recommendation of a general ban of reverse payments (even without the possibilities for rebuttals), a number of critical questions can be raised, which cannot be discussed here. However, much more research from such a perspective is necessary before an economically well-substantiated answer can be offered how an appropriately structured antitrust rule should look like.[49] The question that ultimately has to be answered is to what extent a further differentiation in more case groups beyond the distinction between patent settlements with or without reverse payments is worthwhile for better assessing patent settlements. So far this question has not been answered.

This contribution cannot give a detailed assessment of the current policy in regard to patent settlements. However, based upon the so far existing economic knowledge the current competition policy in the U.S. (after the Actavis decision of the U.S. Supreme Court) and the EU can be defended to some

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[47] For the error-cost approach in law and economics, see Easterbrook (1992) and Christiansen/Kerber (2006) with many references.

[48] E.g. Crane 2002, McDonald 2003, and Edlin et al. 2014.

[49] Since such an analysis of decision errors also needs information about the frequency of certain types of patent settlements, also empirical studies about patent settlements (as Hemphill 2009) are important.

extent, although we think that it still might be a bit too cautious in regard to patent settlements. Since it is undisputed that reverse payments are a very effective instrument for delaying generic entry (also in more realistic and complex bargaining contexts), the strategy to focus the analysis primarily on (the size of) reverse payments is a correct one. From this perspective also a presumption of the illegality of reverse payments, which can be rebutted with a limited number of reasonings, can be defended. In that respect, it has to be seen that such a presumption need not be too far away from the approach of the U.S. Supreme Court, which sees the necessity that a large reverse payment has to be explained for viewing such patent settlements as complying with antitrust rules.[50] However, this need not mean that these assessments are getting easy and simple. Since reverse payments in settlement cases can be hidden in complex package of side-deals (e.g., licensing agreements and supply of ingredients), even proving the existence and size of reverse payments might need a deep case analysis. However, vice versa, we also would not recommend that the lack of reverse payments in patent settlements should be viewed as a strong indicator for their compatibility with competition law.[51]

The complexity of a correct antitrust assessment of patent settlements which might protect unjustified monopoly positions through potentially invalid patents raises the question whether more suitable policy solutions could be found by directly addressing the underlying problem of the fundamental defects of the patent system that produces too many weak patents. This is in line with Farrell/Shapiro (2008) and Encaoua/Lefouili (2009) who discuss the weak patent problem in the context of the optimal design of the patent system. From that perspective the entire discussion about patent reform for dealing with the many problems and defects of the current patent system is relevant.[52] This can encompass the strengthening of patent examination in patent offices (as Farrell/Shapiro 2008 suggest for certain groups of patents) with the objective of directly reducing the number of weak valuable patents, e.g. also by including competitors and other interested firms already in the process of granting patents (ibid. p. 1361). Another option is the facilitating and strengthening of the possibilities of weeding out invalid patents through patent opposition and patent litigation (ibid., Fischmann 2016, pp. 480). Other proposals refer to the idea of solving the challenging incentive problem by subsidizing patent challenges, e.g. through a cashbounty program, or allowing more easily joint challenges by several generic entrants (Miller 2004, Encaoua/Lefouili 2009, pp. 21). As our analysis of the three channels of effects (price, innovation, and challenging incentive effects) of patent settlements already showed, from an economic perspective an integrated view of competition and patent law is necessary. Therefore we should search for the best combination of policy solutions in competition and patent law for solving the competition and innovation problems through weak patents.

[50] See the recent proposal of an "Actavis inference" by Edlin et al. (2015), a proposed framework in light of the Actavis ruling by Carrier (2014a) as well as a critical analysis by Kobayashi et al. (2015).
[51] This is also in line with the Actavis decisions of the U.S. Supreme Court, which did not explicitly constitute a safe harbour rule for patent settlements without reverse payments (Wright 2013, p.15).
[52] Gallini 2002, Shapiro 2004, Bessen/Meurer 2005, Shapiro 2008.

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Essay 3:
Optimal Incentives for Patent Challenges in the Pharmaceutical Industry

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Optimal Incentives for Patent Challenges in the Pharmaceutical Industry

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Abstract

Since the patent system relies on private litigation for challenging weak patents, and patent settlements might influence the incentives for challenging patents, the question arises whether the antitrust assessment of patent settlements should also consider their impact on the incentives to challenge potentially invalid patents. Patent settlements in the pharmaceutical industry between originator and generic firms have been scrutinized critically by competition authorities for delaying the market entry of generics and therefore harming consumers. In this paper we present a model that analyzes the tradeoff between limiting the delay of generic entry through patent settlements and giving generic firms more incentives for challenging weak patents of the originator firms. We show that allowing patent settlements with a later market entry of generics than the expected market entry under patent litigation can increase consumer welfare under certain conditions. We introduce a policy parameter for determining the optimal additional period for collusion that would maximize consumer welfare and show that the size of this policy parameter depends on the size of the challenging costs, the intensity of competition, and the duration between the generics' market entry decisions.

Keywords: patent settlements, collusion, patent challenges
JEL classification: L10, L40, O34

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1. Introduction

It is a well-established empirical insight that patent offices grant many patents that are later found invalid when challenged in court (Lemley/Shapiro 2005, Lemley 2001, Allison/Lemley 1998). Hence, patents do not grant an ironclad “right to exclude”, but a weaker “right to try to exclude” (Shapiro 2003, p. 395). Therefore, economists have developed the notion of "probabilistic patents", which defines the strength of a patent as the probability that a patent can be upheld in patent litigation (Lemley/Shapiro 2005). Patents which are granted erroneously lead to unjustified monopolies that harm consumers through monopoly prices. In addition, they might also block further innovation. Since society has an interest in weeding out these unjustified patents (Ayres/Klemperer 1999, Shapiro 2003, Lemley/Shapiro 2005), patent systems usually have procedures for patent opposition and patent litigation, in which other firms can sue for invalidation of patents. Since, however, the patent systems rely on private litigation for patent challenges, the question emerges whether firms have socially optimal incentives for challenging potentially invalid ("weak") patents. One specific incentive problem for challenging patents is that the challenging firm cannot internalize all the benefits for invalidating a patent, because other firms (and through more competition also the consumers) can benefit from removing an unjustified monopoly. This has been described as a public good problem of challenging patents (or as the "multiple challenger" problem), which can lead to inefficiently small challenging incentives for individual firms (Farrell/Merges 2004, Farrell/Shapiro 2008). Obvious solutions for inefficiently small challenging incentives are spending more money for better examinations in the patent offices or granting subsidies for firms that challenge weak patents. However, the additional costs would have to be borne by the taxpayer (Miller 2004).

Another well-known problem for solving the issue of weak patents is that patent holders try to defend their unjustified patents through patent settlements. Here, they pay firms for not challenging their weak patents with the consequence of delaying market entry and price competition (pay-for-delay agreements) and thus harming consumers. Patent settlements can therefore be an instrument for undermining patent litigation as an instrument for solving the weak patent problem. In this paper, we want to analyze whether the problem of inefficiently small challenging incentives should be considered in the antitrust policy dealing with such patent settlements. Particularly in the pharmaceutical industry, patent settlements have been scrutinized critically by competition authorities both in the U.S. and the EU. Since prices for pharmaceutical products are sharply decreasing after the entry of generics, any unjustified

delay of the generic firms' entry can lead to high additional health costs for consumers and society. Especially patent settlements, in which the (patent-holding) originator firms pay large sums to generic firms ("reverse payments") and agree on future entry dates of generics have been the object of competition and antitrust law proceedings. Competition authorities in the U.S. and the EU have taken action against such patent settlements in a number of cases (as, e.g., the "Lundbeck" case in the EU (Case AT.39226 – Lundbeck)). Particularly important was the ruling of the US Supreme Court in the "Actavis" case, in which it decided that patent settlements with high unexplained reverse payments can be anticompetitive and violate antitrust law (570 U. S. ____ (2013) FTC v. Actavis).

The basic arguments about the potentially anticompetitive effects of patent settlements with high reverse payments are widely accepted in the economic and legal discussion. However, there is still much controversy about the specific assessment criteria for patent settlements in the pharmaceutical industry and to what extent reverse payments may also be justified (Shapiro 2003, Willig/Bigelow 2004, Elhauge/Krüger 2012, Woodcock 2016a). In economic models, it could be shown that under specific circumstances also patent settlements with reverse payments might not harm consumers or might even be necessary for achieving efficient settlement (see Section 2). One of the concerns about a too restrictive antitrust policy against patent settlements is that prohibiting patent settlements with reverse payments (beyond litigation costs) would decrease the generics' incentives for challenging weak patents.

In this paper, we are presenting a model that analyzes the tradeoff between, on the one hand, the negative price effects of longer collusion between originator firms and generics through an agreed later generic entry (including reverse payments), and, on the other hand, the positive effects on consumer welfare through incentivizing the challenging of more weak patents by generics. Such a solution would also have the advantage that the costs of challenging more weak patents would be borne by the consumers of pharmaceutical products who benefit from the removal of unjustified patents. Following this rationale, we introduce in our model a policy parameter that stipulates the additional collusion time that competition authorities can grant to the parties of patent settlements in order to maximize consumer welfare.
In the model, we can show that there exists an optimal policy parameter which would lead to a higher consumer welfare than under the litigation solution (without a settlement), which so far has been used as a normative benchmark for the antitrust assessment of patent settlements

(Shapiro (2003)). Therefore, the consideration of challenging incentive effects can lead to a different assessment of patent settlements, and challenging incentives can be another well-founded reason for the justification of patent settlements with later generic entry and reverse payments. However, our model also proves that it depends on parameter constellations, as, e.g. the size of challenging costs, whether the optimal policy parameter is indeed positive or whether it is negative. The latter case would imply that even patent settlements without reverse payments can lead to an inefficiently long collusion period, i.e. leading to inefficiently strong challenging incentives, and therefore rendering them anticompetitive. Therefore, our results show that the consideration of challenging incentives changes the criteria for the assessment of patent settlements. However, they do not necessarily lead to the recommendation of a longer period of collusion in patent settlements and to the justification of reverse payments. For the case of a positive optimal policy parameter, we show in comparative statics analysis that this policy parameter would increase with rising challenging costs, with a longer lag between the generics' entry decisions, and with a higher intensity of competition on the market for pharmaceuticals.

The paper is structured as follows: In Section 2, we discuss, how the problem of challenging incentives has so far been considered in the context of the legal and economic discussion about the antitrust assessment of patent settlements in the pharmaceutical industry. In addition, we explain the basic idea of our approach. Sections 3 - 5 present the basic model. After explaining the model framework in Section 3, we derive the optimal policy parameter in Section 4. Afterwards, we conduct a welfare analysis in Section 5 that shows that the optimal policy parameter maximizes consumer welfare, but also that it can be positive or negative. Section 6 provides our analyses of comparative statics. In Section 7, we briefly discuss the results and potential conclusions.

2. Patent Settlements and Incentives for Patent Challenges

In the U.S., patent settlements with reverse payments in the pharmaceutical industry were challenged by the Federal Trade Commission (FTC) since 1999, because they could be collusive behavior between originators and generics for delaying market entry of generics and therefore harming consumers (FTC (2002)). The main discussion in the U.S. focused on the question whether the existence of a large reverse payment (i.e., larger than litigation costs) should be sufficient for a presumption of the illegality of a patent settlement, or whether a broader rule-of-reason approach should be applied. The latter would require a more case-

specific analysis of the efficiency-enhancing and anticompetitive effects of patent settlements and therefore allow for easier justifications for patent settlements with reverse payments. After contradictory decisions by U.S. courts, the U.S. Supreme Court decided in "Actavis" that large, unexplained reverse payments in patent settlements can be a signal for the weakness of patents and therefore for the anticompetitiveness and illegality of such patent settlements (570 U. S. ____ (2013) FTC v. Actavis). However, it also insisted on a rule-of-reason approach. In the EU, the European Commission also viewed patent settlements with restrictions of market entry and reverse value transfers as potentially anticompetitive agreements that require a close scrutiny by competition law. In the meantime, the Commission has decided in several patent settlement cases with reverse payments that they are violating Art. 101 TFEU. In the recent "Lundbeck" case, the European Court has confirmed the Commission (General Court Case T-467/13). Especially relevant for our research question is that the Commission emphasized in its competition guidelines about patent settlements that society also has an interest in removing wrongly granted patents to promote competition and innovation (Guidelines on the application of Article 101 of the Treaty on the Functioning of the European Union to technology transfer agreements, p. 44).

In the economic discussion, there is a broad consensus that patent settlements with reverse payments from originators to generics can be an effective instrument for protecting weak patents against their invalidation through patent challenges. In addition, the criterion of Shapiro (2003), which states that patent settlements should not lead to lower consumer welfare than under patent litigation, has been broadly accepted in the economic and legal discussion as a relevant normative criterion for the antitrust assessment of patent settlements. In the basic settlement model about the price effects of patent settlements on consumer welfare, it has been shown that if reverse payments are larger than litigation costs, patent settlements lead to an entry date of generics that is delayed beyond the expected entry date under litigation, i.e. compared to the benchmark of the litigation solution, consumers are harmed (Shapiro (2003), Elhauge/Krüger (2012), Frank/Kerber (2016)). This result strongly supports the concerns about reverse payments. However, subsequent economic analyses have also clarified that under less simple and more realistic assumptions about the negotiation situation (e.g., information asymmetries, risk aversion, multiple entrants etc.), the conclusions about reverse payments are less clear. On the one hand, there might be economically well-founded reasons for why patent settlements with large reverse payments might also be efficient and not harm consumers. On the other hand, patent settlements without reverse

payments can also be anticompetitive. Therefore, the existence of reverse payments might not be such a clear criterion for identifying anticompetitive patent settlements, and hence in most cases a deeper investigation might be necessary (Willig/Bigelow (2004), Dickey et al. (2010)).

A serious problem of the current discussion is that it has so far almost exclusively focused on the effects of patent settlements on consumer welfare via price effects, i.e. on the question, whether patent settlements lead to an inefficiently late generic entry and therefore to an inefficiently late start of price competition through generics. However, patent settlements can also affect consumer welfare through two additional channels (Frank/Kerber (2016)). Since antitrust limits for patent settlements also influence the profits of the originators, the question emerges whether these limits to patent settlements might have negative effects on the innovation incentives for originators and therefore might harm consumers through the development of fewer pharmaceuticals. So far, only Elhauge/Krüger (2012) and Woodcock (2016a, 2016b) have taken this innovation incentive effect into account when analyzing the effects of patent settlements. Although we should be cautious about too far-reaching conclusions from their models, their results suggest that competition authorities don't have to worry too much about negative effects on innovation incentives. The second additional channel is the effect of antitrust limits of patent settlements on the challenging incentives for generics. For example, in the above-mentioned "Actavis" ruling of the U.S. Supreme Court, Chief Justice Roberts states in his dissenting opinion that putting limits on the possibility to engage in patent settlements with certain entry dates reduces the incentives to challenge patents (570 U. S. ____ (2013) FTC v. Actavis, Roberts, C.J. dissenting pp. 17). In addition, other scholars are also concerned that a too restrictive policy in regard to the possibilities of generics to make profits from patent settlements through reverse payments would decrease their incentives to challenge patents (e.g. Dickey et al. (2010, p. 399)).

These concerns about the generics' challenging incentives suggest that there might be a tradeoff between limiting the delay of generic entry through patent settlements for ensuring early price competition and offering generics more incentives for challenging additional weak patents of originators. In our model, we want to study this trade off and analyze whether consumer welfare increases, if competition authorities would grant an additional period of collusion (beyond the expected entry date of the litigation solution) in order to incentivize the challenging of additional patents. The economic intuition is, that the additional costs for consumers of pharmaceutical products from a later generic entry (in form of a later decrease

in prices) might be smaller than their additional benefits from the challenging of more weak patents, which otherwise would allow their owners monopoly profits until their expiration.

The structure of our model is partly based upon the model of Gratz (2012), who was the first to offer an integrated analysis of price and challenging incentive effects in regard to patent settlements. In her model, she finds that a specifically tailored rule-of-reason assessment of patent settlements, where reverse payments from the originator to the generic are allowed, leads courts to erroneously uphold anticompetitive patent settlements. This increases joint settlement profits and hence the challenging incentives for generics. Therefore, in her model judicial errors (due to information problems in the application of the rule-of-reason) lead to overall positive effects on consumer welfare through erroneously allowing later generic entry than in the benchmark litigation solution. In contrast to her approach, we introduce a policy parameter and analyze the optimal additional delay (compared to the litigation solution) that would maximize consumer welfare if challenging incentives are also taken into account.[1] As in the model of Gratz (2012), we also suppose the existence of two generic entrants that can challenge the patent and sequentially enter the market at two endogenously determined dates with an exogenously given lag between the entry decision of the first and the second generic. Therefore, we do not model the public good problem that emerges if several entrants could simultaneously challenge a patent (multiple challenger problem)[2] as well as we do not model strategic interaction between generics.

3. Model Framework

Our model follows the basic framework introduced by Gratz (2012). In this framework, an originator (O) holds a patent with remaining patent duration $1-t$, where $t \in [0,1]$, and patent strength γ, which is a random variable following a continuous uniform distribution over the unit interval, i.e. $\gamma \sim U[0,1]$. Hence, we can interpret γ as reflecting the probability that the patent is found valid in court. It is assumed that all patents have the same value and that the realizations of γ are common knowledge. Two generics (G_1 and G_2) are potential entrants in

[1] Compared to the policy parameter in our model, the errors which courts make in applying the rule-of-reason in the model of Gratz (2012) have a different effect, because this error always leads to higher challenging incentives for generics, while our policy parameter for additional collusion can be positive or negative.

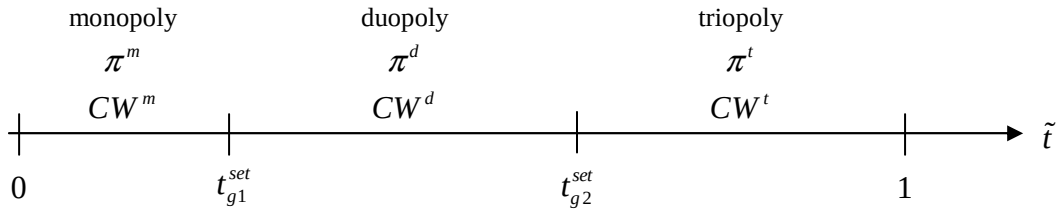
[2] In the U.S., the incentive problems resulting from the public good problem were addressed by the Hatch-Waxman Act, which grants the first challenger a 180 days marketing exclusivity of generic entry, before other entrants are allowed to enter the market (FTC (2011, p. 138), Hemphill (2006)). Therefore, sequential entry of generics has some similarities to the consequences of this U.S. regulation, although we do not intend to model the specific conditions of the U.S. Hatch-Waxman pharmaceutical sector regulation.

the market by challenging the patent at a specific time with challenge costs f_g. G_1 and G_2 make their entry decisions in a fixed sequence and, depending on the situation, it is possible that both enter, only G_1 enters, or none enters. The generics' challenging decisions are based on the rationale whether the generated net profits from such a patent challenge are greater than zero. It is assumed that firms maintain the option to litigate and hence to reap, in addition to the settlement surplus, their expected litigation profits. G_1 decides on challenging the patent at $t=0$, whereas G_2 decides to challenge at $t=\lambda$, where $\lambda \in (0,1)$. If the patent is declared invalid, entry by the first generic would occur at $t=0$ and entry of the second generic at $t=\lambda$. In case the patent is held valid, entry by both generics would occur at $t=1$. This implies that G_1's expected entry date under litigation is $t_{g1}^{lit}=\gamma\cdot 1+(1-\gamma)\cdot 0=\gamma$, while G_2's expected entry date is $t_{g2}^{lit}=\gamma\cdot 1+(1-\gamma)\lambda > t_{g1}^{l}$. Hence, G_1 always enters prior to G_2.

If a generic challenges a patent, the originator and the generic can settle their patent dispute through a patent settlement with the agreement on a specific future entry date and a potential payment from the originator to the generic (reverse payment). We assume that the settling firms equally share the settlement surplus.

The parties' actual entry dates under a settlement, t_{g1}^{set} and t_{g2}^{set}, are endogenous with $t_{g1}^{set}\in[0,1]$ and $t_{g2}^{set}\in[\lambda,1]$. Since market entry occurs sequentially, the originator can reap monopoly profits π^m for the period $\left[0,t_{g1}^{set}\right)$, whereas for $\left[t_{g1}^{set},t_{g2}^{set}\right)$, originator and first generic generate duopoly profits $\pi_o^d+\pi_g^d=\pi^d$, where $\pi_o^d\geq\pi_g^d$. Finally, for $\left[t_{g2}^{set},1\right]$, the firms realize triopoly profits $\pi_o^t+2\pi_g^t=\pi^t$, where $\pi_o^t\geq\pi_g^t$. The resulting consumer welfare is given by CW^m, CW^d, and CW^t, respectively. We assume that $\pi^m>\pi^d>\pi^t$ as well as $CW^m<CW^d<CW^t$, which corresponds to standard conditions under competitive markets. *Fig. 1* summarizes this situation.

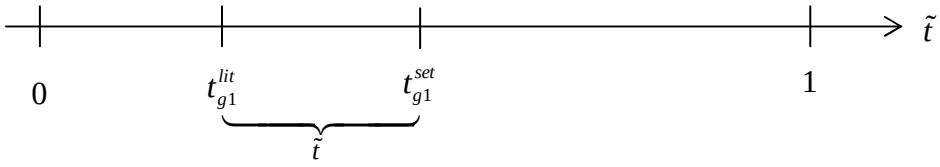
Figure 1: Market structure, profits, and consumer welfare in the settlement solutions



According to the criterion of Shapiro, competition authorities would prohibit all patent settlements through which consumers are harmed by generic entries that are later than

expected under litigation. This implies that the firms are not allowed to specify entry dates beyond $t_{g1}^{lit} = \gamma$ and $t_{g2}^{lit} = \gamma + (1-\gamma)\lambda$. However, deviating from Gratz (2012), we introduce a policy parameter $\tilde{t}$, which explicitly allows the competition authorities to grant the parties an additional time period for collusion. In particular, O and G_1 can agree to share monopoly profits until $t_{g1}^{set} = t_{g1}^{lit} + \tilde{t} = \gamma + \tilde{t}$, where t_{g1}^{set} denotes the (certain) entry date of G_1 under this policy parameter. Since the original remaining patent duration, i.e. the remaining duration for $t = 0$, is equal to one, $\tilde{t}$ can be interpreted as a percentage share of the original remaining patent duration that is *additionally* granted for collusion. We illustrate this situation in *Fig. 2*.

Figure 2: Policy parameter $\tilde{t}$ as a share of the original remaining patent duration



4. Equilibrium Analysis: The Optimal Policy Parameter

Since competition authorities will not challenge settlements with $t_{g1}^{set} \leq t_l + \tilde{t}$, O and G_1 will optimally choose the corner solution, i.e. they choose $t_{g1}^{set} = t_{g1}^{lit} + \tilde{t} = \gamma + \tilde{t}$. This implies that the corresponding entry date of a second settlement is $t_{g2}^{set} = t_{g1}^{set} + (1 - t_{g1}^{set})\lambda$. Hence, the joint settlement profits under $\tilde{t}$ are given by

$$(1) \quad \Pi^{set} = \begin{cases} (\gamma + \tilde{t})\pi^m + (1-(\gamma+\tilde{t}))\left[\lambda(\pi_o^d + \pi_g^d) + (1-\lambda)(\pi_o^t + 2\pi_g^t)\right] \text{ for } \gamma \in \left[0, \gamma_{g2}^{set}\right], \\ (\gamma + \tilde{t})\pi^m + (1-(\gamma+\tilde{t}))(\pi_o^d + \pi_g^d) \text{ for } \gamma \in \left(\gamma_{g2}^{set}, \gamma_{g1}^{set}\right], \end{cases}$$

where γ_{g1}^{set} and γ_{g2}^{set} denote the critical levels of patent strength, for which generic companies are indifferent between challenging a patent or not. Therefore, the generated surplus compared to litigation is

$$(2) \quad s_1 = \tilde{t}\left(\pi^m - \lambda(\pi_o^d + \pi_g^d) - (1-\lambda)(\pi_o^t + 2\pi_g^t)\right) \text{ for } \gamma \in \left[0, \gamma_{g2}^{set}\right],$$

$$(3) \quad s_2 = \tilde{t}\left(\pi^m - (\pi_o^d + \pi_g^d)\right) \text{ for } \gamma \in \left(\gamma_{g2}^{set}, \gamma_{g1}^{set}\right].$$

which allows us to determine the critical levels of patent strength. Respecting that the relevant expected litigation profits for G_1 and G_2 are given by $\pi_{g1}^{lit}(\gamma) = (1 - t_{g1}^{lit})\pi_g^d = (1-\gamma)\pi_g^d$ and $\pi_{g2}^{lit}(\gamma) = (1 - t_{g2}^{lit})\pi_g^t = (1-\gamma)(1-\lambda)\pi_g^t$, we find that γ_{g1}^{set} and γ_{g2}^{set} are determined by

(4) $$\pi_{g1}^{lit}(\gamma)+\frac{s_2}{2}-f_g=0 \quad \Leftrightarrow \quad \gamma_{g1}^{set}=1-\frac{f_g-\frac{s_2}{2}}{\pi_g^d},$$

(5) $$\pi_{g2}^{lit}(\gamma)+\frac{s_1}{3}-f_g=0 \quad \Leftrightarrow \quad \gamma_{g2}^{set}=1-\frac{f_g-\frac{s_1}{3}}{(1-\lambda)\pi_g^t}<\gamma_{g1}^{set}.$$

Given Equations (4) and (5) we can conclude that G_1 challenges patents for $\gamma\in\left[0,\gamma_{g1}^{set}\right]$, while G_2 challenges for $\gamma\in\left[0,\gamma_{g2}^{set}\right]$, which leads to the following market structures: If neither G_1 nor G_2 challenges any patents, i.e. for $\gamma\in\left(\gamma_{g1}^{set},1\right]$, the originator's monopoly covers the entire remaining patent duration. For $\gamma\in\left(\gamma_{g2}^{set},\gamma_{g1}^{set}\right]$ only G_1 enters the market, so the originator company holds a monopoly for $t_{g1}^{set}-0=\gamma+\tilde{t}$. Then, G_1 enters at t_{g1}^{set}, creating a duopoly for the time period $1-t_{g1}^{set}=1-\gamma-\tilde{t}$. However, for $\gamma\in\left[0,\gamma_{g2}^{set}\right]$ we find that G_2 additionally enters the market. Therefore, monopoly lasts for $t_{g1}^{set}-0=\gamma+\tilde{t}$, duopoly for $t_{g2}^{set}-t_{g1}^{set}=(1-\gamma-\tilde{t})\lambda$, and triopoly for $1-t_{g2}^{set}=(1-\gamma-\tilde{t})(1-\lambda)$. Hence, respecting CW^m, CW^d, and CW^t, we know that consumer welfare under $\tilde{t}$ is described by

(6) $$\begin{aligned}CW^{set}(\tilde{t})=&\int_0^{\gamma_{g2}^{set}(\tilde{t})}\left[(\gamma+\tilde{t})CW^m+(1-\gamma-\tilde{t})\left[\lambda CW^d+(1-\lambda)CW^t\right]\right]d\gamma\\&+\int_{\gamma_{g2}^{set}(\tilde{t})}^{\gamma_{g1}^{set}(\tilde{t})}\left[(\gamma+\tilde{t})CW^m+(1-\gamma-\tilde{t})CW^d\right]d\gamma+\int_{\gamma_{g1}^{set}(\tilde{t})}^{1}CW^m\,d\gamma\\&=\left[(1-\tilde{t})\gamma_{g1}^{set}(\tilde{t})-\frac{\gamma_{g1}^{set}(\tilde{t})^2}{2}\right](CW^d-CW^m)+CW^m\\&+\left[(1-\tilde{t})\gamma_{g2}^{set}(\tilde{t})-\frac{\gamma_{g2}^{set}(\tilde{t})^2}{2}\right](1-\lambda)(CW^t-CW^d).\end{aligned}$$

Maximizing Equation (6) with respect to $\tilde{t}$ yields

(7) $$\begin{aligned}\frac{\partial CW^{set}}{\partial\tilde{t}}=&\underbrace{\frac{\partial\gamma_{g1}^{set}}{\partial\tilde{t}}(1-\gamma_{g1}^{set}-\tilde{t})(CW^d-CW^m)}_{\text{Incentive Effect - G}_1}-\underbrace{\gamma_{g1}^{set}(CW^d-CW^m)}_{\text{Entry Delay Effect - G}_1}\\&+\underbrace{\frac{\partial\gamma_{g2}^{set}}{\partial\tilde{t}}(1-\gamma_{g2}^{set}-\tilde{t})(1-\lambda)(CW^t-CW^d)}_{\text{Incentive Effect - }G_2}-\underbrace{\gamma_{g2}^{set}(1-\lambda)(CW^t-CW^d)}_{\text{Entry Delay Effect - G}_2}.\end{aligned}$$

The interpretation of (7) is straightforward: If competition authorities are more generous with patent settlements, the joint settlement profits increase and hence generic companies challenge more patents. This is reflected by the incentive effects. In particular, G_1 additionally challenges $\partial\gamma_{g1}^{set}/\partial\tilde{t}$ patents, for which we have an increase of consumer welfare by $\left(CW^d - CW^m\right)$ for the period after market entry under the marginal settlement, i.e. for $1-t_{g1}^{set} = 1-\gamma_{g1}^{set}-\tilde{t}$. However, due to G_1's delayed market entry, consumer welfare decreases by $\left(CW^d - CW^m\right)$ for all γ_{g1}^{set} patents, which would have been challenged anyway. The same logic applies to G_2. Hence, the optimal policy is determined by the point where these two opposing effects marginally compensate each other, i.e. it is determined by $\partial CW^{set}/\partial\tilde{t} = 0$. Obviously, we find that a marginal increase in $\tilde{t}$ creates a tradeoff between incentivizing more patent challenges and creating more collusion. The next step is to find the optimal policy, which is denoted by $\tilde{t}_{opt}$.

Since we have that

$$(8)\ \frac{\partial\gamma_{g1}^{set}}{\partial\tilde{t}} = \frac{\left(\pi^m - \left(\pi_o^d + \pi_g^d\right)\right)}{2\pi_g^d} \text{ and } (9)\ \frac{\partial\gamma_{g2}^{set}}{\partial\tilde{t}} = \frac{\left(\pi^m - \lambda\left(\pi_o^d + \pi_g^d\right) - (1-\lambda)\left(\pi_o^t + 2\pi_g^t\right)\right)}{3(1-\lambda)\pi_g^t},$$

we find that $\tilde{t}_{opt}$ can be explicitly described by

$$(10)\quad \tilde{t}_{opt} = \left[CW^d - CW^m - \left(CW^d - CW^t\right)(1-\lambda) + \frac{\varphi_2\left(CW^m - CW^d\right)f_g}{2\left(\pi_g^d\right)^2} + \frac{\left(CW^m - CW^d\right)f_g}{\pi_g^d} - \frac{\varphi_1\left(CW^t - CW^d\right)f_g}{3(1-\lambda)\left(\pi_g^t\right)^2} + \frac{\left(CW^m - CW^d\right)f_g}{\pi_g^t} \right] \Bigg/ \left[-\frac{\varphi_2\left(CW^d - CW^m\right)\left(\varphi_2 + 4\pi_g^d\right)}{4\left(\pi_g^d\right)^2} - \frac{\left(\varphi_1\right)^2\left(CW^t - CW^d\right)}{9(1-\lambda)\left(\pi_g^t\right)^2} - \frac{2\varphi_1\left(CW^t - CW^d\right)f_g}{3\pi_g^t} \right],$$

where $\varphi_1 = \pi^m - \lambda\left(\pi_o^d + \pi_g^d\right) - (1-\lambda)\left(\pi_o^t + 2\pi_g^t\right)$ and $\varphi_2 = \pi^m - \left(\pi_o^d + \pi_g^d\right)$. As we know that $CW^m < CW^d < CW^t$, $\lambda \in (0,1)$ and $\varphi_1, \varphi_2, \pi_g^d, \pi_g^t > 0$, we can show that

$$\partial\left(CW^{set}\right)^2 \Big/ \partial\left(\tilde{t}\right)^2 = \left(CW^d - CW^m\right)\left(-\left(\varphi_2\right)^2 \Big/ \left(4\left(\pi_g^d\right)^2\right) - \varphi_2/\pi_g^d\right)$$
$$+\left(CW^t - CW^d\right)(1-\lambda)\left(-\left(\varphi_1\right)^2 \Big/ \left(9(1-\lambda)^2\left(\pi_g^t\right)^2\right) - 2\varphi_1 \Big/ \left(3(1-\lambda)\pi_g^t\right)\right) < 0.$$

Hence, we can conclude that $\tilde{t}_{opt}$ is a unique maximum solution.

5. Welfare Analysis

In order to show that the implementation of $\tilde{t}_{opt}$ is beneficial for consumers, we have to compare our results to the benchmark case of the litigation solution. Using Equation (6) we can easily compute consumer surplus under litigation by evaluating $CW^{set}(\tilde{t})$ at $\tilde{t}=0$. Hence, consumer welfare under litigation is given by $CW^{set}(0)$, whereas consumer welfare under the optimal policy $\tilde{t}_{opt}$ is determined by $CW^{set}(\tilde{t}_{opt})$. Our results are summarized in Proposition 1:

Proposition 1: For $\tilde{t}_{opt} \neq 0$ the implementation of $\tilde{t}_{opt}$ strictly increases consumer welfare, i.e. we have that $CW^{set}(\tilde{t}_{opt}) > CW^{set}(0)$. For the special case where $\tilde{t}_{opt}=0$, we obviously have that $CW^{set}(\tilde{t}_{opt}) = CW^{set}(0)$.
Proof: See Appendix A.

Proposition 1 shows that the implementation of $\tilde{t}_{opt}$ is indeed welfare increasing for consumers. Except for the case of $\tilde{t}_{opt}=0$, this result holds in general, i.e. it holds for $\tilde{t}_{opt}>0$ as well as for $\tilde{t}_{opt}<0$. In Appendix B, we show that Proposition 1 also holds for the case of one generic entrant. Therefore, our results do not depend on the specific assumption of two generic entrants. In addition, note that our results neither require any additional assumptions with respect to the mode of competition nor with respect to the intensity of competition.
Given the paper's focus, it is also a very important result that, depending on parameter constellations, the optimal policy parameter $\tilde{t}_{opt}$ can be positive or negative. However, firms would never accept any settlement profits that are lower than profits under litigation. Therefore, a requirement of competition authorities that the entry date in a settlement should be prior to the expected entry date under litigation would make settlements impossible and lead to the litigation solution. In addition, market entry cannot be delayed beyond the original patent duration, i.e., $\tilde{t}_{opt} \leq 1$. Hence, in our model framework feasible solutions for patent settlements require $\tilde{t}_{opt} \in [0,1]$, which holds for $f_g \in \left[\underline{f}_g, \overline{f}_g\right]$, where

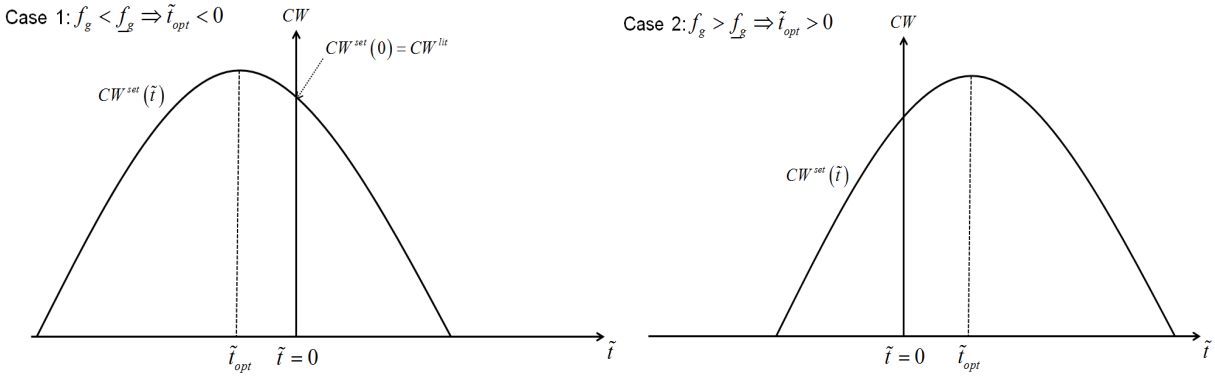
$$\underline{f}_g = \Big[-6(1-\lambda)\left(CW^m - CW^t(1-\lambda) - CW^d\lambda\right)\left(\pi_g^d\right)^2\left(\pi_g^t\right)^2\Big] \Big/ \Big[2\varphi_1\left(CW^t - CW^d\right)\left(\pi_g^d\right)^2 - 3(1-\lambda)\pi_g^t\left(2\left(CW^d - CW^t\right)\left(\pi_g^d\right)^2 - \left(CW^d - CW^m\right)\left(\varphi_2 + 2\pi_g^d\right)\pi_g^t\right)\Big],$$

$$\overline{f}_g = \Big[\left(CW^d - CW^t\right)\left(\pi_g^d\right)^2\left(4(\varphi_1)^2 + 24\varphi_1(1-\lambda)\pi_g^t\right) - 9(1-\lambda)\left(\varphi_2\left(CW^d - CW^m\right)\left(\varphi_2 + 4\pi_g^d\right) + \left(CW^t - CW^m + \lambda\left(CW^d - CW^t\right)\right)\left(\pi_g^d\right)^2\right)\left(\pi_g^t\right)^2\Big] \Big/ \Big[6\left(2\varphi_1\left(CW^d - CW^t\right)\left(\pi_g^d\right)^2 - 3(1-\lambda)\pi_g^t\left(2\left(CW^t - CW^d\right)\left(\pi_g^d\right)^2 + \left(CW^d - CW^m\right)\left(\varphi_2 + 2\pi_g^d\right)\pi_g^t\right)\right)\Big].$$

Note that we can show that $0 < \underline{f}_g < \overline{f}_g$, which implies that $\tilde{t}_{opt} > 0$ requires challenge costs to be strictly positive and sufficiently high. In case that challenge costs are below the lower threshold level, the optimal policy would result in $\tilde{t}_{opt} < 0$, i.e., firms would strictly prefer to go for litigation. If challenge costs are above the upper threshold, we would have $\tilde{t}_{opt} > 1$. Hence, we end up with the corner solution where $\tilde{t}_{opt} = 1$.

Our finding that $\tilde{t}_{opt}$ can be positive or negative implies that we have to distinguish two cases (see *Fig. 3*). In Case 1 ($f_g < \underline{f}_g$), consumer welfare would be maximized for $\tilde{t}_{opt} < 0$. Economically, this would imply that the optimal date of generic entry is even prior to the expected entry date under litigation. Here, the challenging incentives provided in the litigation solution are inefficiently high. Hence, reducing challenging incentives would be welfare-increasing for consumers. In addition, we can conclude that all settlements that specify an entry date beyond the one under litigation are clearly anticompetitive. However, as we have seen above, as long as the law does not limit the parties' rights to litigate, competition authorities cannot enforce earlier market entry than under litigation. In Case 2 ($f_g > \underline{f}_g$), the situation is entirely different. If $\tilde{t}_{opt} > 0$, challenging incentives under litigation are inefficiently small. Therefore, allowing for a longer period of collusion benefits consumers. Since generic entry delay is only possible if the generics get a share of the settlement surplus, competition authorities have to allow reverse payments to a certain extent. Hence, our analysis shows that allowing for more collusion in patent settlements (with reverse payments) can be procompetitive. However, this only holds for Case 2, i.e. for $\tilde{t}_{opt} > 0$.

Figure 3: Impact of $\tilde{t}_{opt}$ on consumer welfare



In order to explain the intuition behind the results of Proposition 1, we have to analyze the impact of $\tilde{t}_{opt}$ on the range of challenged patents at first. Since we focus on $\tilde{t}_{opt} > 0$, we know that the optimal policy allows for more collusion, i.e. for a delayed market entry of both

generics. Indeed, we can show that the market entry dates $t_{g1}^{set} = t_{g1}^{lit} + \tilde{t} = \gamma + \tilde{t}$ and $t_{g2}^{set} = t_{g1}^{set} + \left(1 - t_{g1}^{set}\right)\lambda$ are extended beyond their counterparts under litigation, i.e. we have that $t_{g1}^{set} > t_{g1}^{lit}$ as well as $t_{g2}^{set} > t_{g2}^{lit}$. Therefore, the settlement surpluses are strictly positive, which induces both generics to challenge more patents. Hence, the critical level of patent strength under such a settlement is larger than under litigation, i.e. $\gamma_{g1}^{set} > \gamma_{g1}^{lit}$ and $\gamma_{g2}^{set} > \gamma_{g2}^{lit}$ (see *Fig. 4*).

Figure 4: Entry delay and incentive effects under $\tilde{t}_{opt} > 0$

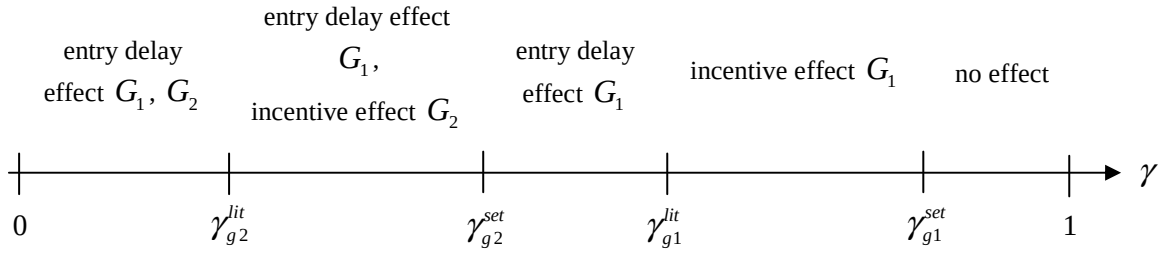


Fig. 4 refers to the case of $\tilde{t}_{opt} > 0$ and depicts entry delay and incentive effects for different intervals of patent strength. These intervals are bound by the critical levels of patent strength under litigation as well as under $\tilde{t}_{opt}$. Thus, we can derive for which patent strengths incentive and entry delay effects are relevant and to which extent they affect consumer welfare. As we can see from *Fig. 4*, G_2 would challenge γ_{g2}^{lit} patents under litigation, while G_1 challenges $\gamma_{g1}^{lit} > \gamma_{g2}^{lit}$ patents. Hence, G_1 strictly challenges more patents than G_2. This result is a consequence from the assumption of sequential entry decisions of the parties: Since G_1 always decides first about entry, it can reap more profits and a broader range of patent challenges is feasible. As we already know, the critical levels of patent strength under $\tilde{t}_{opt}$ are γ_{g2}^{set} and γ_{g1}^{set}, where we find $\gamma_{g1}^{set} > \gamma_{g2}^{set}$ for the same reason.

Analyzing the incentive and entry delay effects, we can see in *Fig. 4* that for $\gamma \in \left[0, \gamma_{g2}^{lit}\right]$, both generics would challenge these patents under litigation anyway. Hence, in this interval the implementation of $\tilde{t}_{opt}$ induces an entry delay effect of G_1 and G_2, which negatively affects consumer welfare. For $\gamma \in \left(\gamma_{g2}^{lit}, \gamma_{g2}^{set}\right]$, we find that G_2 additionally challenges patents that would not have been challenged under litigation, which describes G_2's incentive effect. However, this patent range would still have been challenged by G_1 under litigation, i.e. we have an additional entry delay effect for G_1. Hence, for $\gamma \in \left(\gamma_{g2}^{lit}, \gamma_{g2}^{set}\right]$, we find two effects, which affect consumer welfare in opposite directions. For $\gamma \in \left(\gamma_{g2}^{set}, \gamma_{g1}^{lit}\right]$, G_1's entry delay effect is still present, while there is no effect resulting from G_2, since she does not challenge these (or stronger) patents. For $\gamma \in \left(\gamma_{g1}^{lit}, \gamma_{g1}^{set}\right]$, we have that G_1 additionally challenges patents

under the optimal policy. This describes G_1's incentive effect, which positively affects consumer welfare. For the remaining values of γ, i.e. for $\gamma \in \left(\gamma_{g1}^{set}, 1\right]$, we do not observe any effects, because these patents are neither challenged under litigation nor under $\tilde{t}_{opt}$.

6. Comparative Statics

In this chapter, we analyze the comparative statics of the optimal policy parameter $\tilde{t}_{opt}$. Since we have found that $\tilde{t}_{opt} < 0$ strictly results in litigation, we restrict our analysis to Case 2, i.e. to the case of $\tilde{t}_{opt} > 0$. We will analyze how $\tilde{t}_{opt}$ is changing if i) the challenging costs f_g increase, ii) the lag between the generics' entry decisions increases, and iii) the intensity of competition on the pharmaceutical market increases. For the analyses ii) and iii), we introduce a specific competition model.

The Effects of an Increase in Challenging Costs

As we already know that challenge costs have a crucial impact on the optimal policy, we examine at first, how $\tilde{t}_{opt}$ changes in f_g. The challenge costs include costs for preparing the challenge as well as firm investments for entering the market, i.e. technology and marketing investments to overcome market entry barriers. The corresponding result is given in Proposition 2:

Proposition 2: The optimal policy parameter $\tilde{t}_{opt}$ is strictly increasing in f_g.
Proof: See Appendix A.

In order to interpret the result of Proposition 2, we recall that $\tilde{t}_{opt}$ was determined by Equation (7). Analyzing (7), we find by using (8) and (9) that a marginal increase in f_g does not have an impact on $\partial\gamma_{g1}^{set}/\partial\tilde{t}$ and $\partial\gamma_{g2}^{set}/\partial\tilde{t}$, as we have that $\partial\gamma_{g1}^{set}/\partial\tilde{t}\partial f_g = 0$ and $\partial\gamma_{g2}^{set}/\partial\tilde{t}\partial f_g = 0$. However, a marginal increase in f_g makes patent challenges more costly. Hence, ceteris paribus firms would only challenge relatively weaker patents, i.e. patents with a smaller γ. Therefore, we have that γ_{g1}^{set} and γ_{g2}^{set} are strictly decreasing in f_g, which in turn has an impact on the incentive effects: Formally, a marginal increase in $\tilde{t}$ increases consumer welfare by $\left(\partial\gamma_{g1}^{set}/\partial\tilde{t}\right)\left(1-\gamma_{g1}^{set}-\tilde{t}\right)\left(CW^d - CW^m\right)$, which describes the incentive effect of G_1. If f_g increases, this incentive effect is stronger, because γ_{g1}^{set} decreases. The interpretation is intuitive: Since γ_{g1}^{set} decreases, $t_{g1}^{set}\left(\gamma_{g1}^{set}\right) = \gamma_{g1}^{set} + \tilde{t}$ decreases as well, i.e. firms would ceteris paribus agree on earlier market entry in the marginal settlement. Hence, consumers benefit

from CW^d for a longer period of time. As this holds for all $\partial\gamma_{g1}^{set}/\partial\tilde{t}$ additionally challenged patents as well, a marginal increase in $\tilde{t}$ has a stronger impact on CW^{set} if f_g marginally increases. The same logic applies to G_2's incentive effect, where a marginal increase in $\tilde{t}$ positively affects CW^{set} by $\left(\partial\gamma_{g2}^{set}/\partial\tilde{t}\right)\left(1-\gamma_{g2}^{set}-\tilde{t}\right)(1-\lambda)\left(CW^t-CW^d\right)$. This incentive effect for G_2 is also stronger if f_g increases, because γ_{g2}^{set} decreases. Hence, an increase in $\tilde{t}$ compensates for fewer patents being challenged as a consequence of an increasing f_g.

Apart from the incentive effects, we also have to take into account the entry delay effects for consumer welfare resulting from a marginal increase in $\tilde{t}$, i.e. from allowing for a marginally delayed market entry. In particular, we find that because of G_1's delayed entry, consumer welfare decreases by CW^d-CW^m for all $\gamma\in\left[0,\gamma_{g1}^{set}\right]$. In case of G_2, we have that consumer welfare marginally decreases by $(1-\lambda)\left(CW^t-CW^d\right)$ for all $\gamma\in\left[0,\gamma_{g2}^{set}\right]$. As we have already seen, a marginal increase in f_g leads to lower values for the critical patent strengths γ_{g1}^{set} and γ_{g2}^{set}. Hence, the entry delay effects $\gamma_{g1}^{set}\left(CW^d-CW^m\right)$ for G_1 and $\gamma_{g2}^{set}(1-\lambda)\left(CW^t-CW^d\right)$ for G_2, respectively, strictly decrease, because the range of patents, which is challenged anyway, ceteris paribus decreases. This outcome is intuitive: The entry delay effect for consumer welfare is based on a larger extent of collusion between $\left[0,\gamma_{g1}^{set}\right]$ and $\left[0,\gamma_{g2}^{set}\right]$. Since both patent strength ranges decrease in f_g, entry delay effects for G_1 and G_2 also decrease. Consequently, with respect to the marginal impact of $\tilde{t}$ on CW^{set}, a marginal increase in f_g leads to an increase in the generics' incentive effects, whereas entry delay effects for both generics decrease. Hence, we obviously find that $\tilde{t}_{opt}$ is strictly increasing in f_g.

Introducing a Specific Competition Model for Parameter Analysis

The remaining exogenous parameters of our model can be divided into two different groups: While λ is an independent exogenous variable, we know that π^m, $\pi^d=\pi_o^d+\pi_g^d$, $\pi^t=\pi_o^t+\pi_g^t$ as well as CW^m, CW^d and CW^t are related as they all depend on the market structure and the mode of competition. Hence, the comparative static analysis of these "market-specific" parameters is very complex and requires many restrictive assumptions. For instance, an increase in π^m might stem from additionally exploited consumer surplus (which implies a decrease of CW^m) or from a higher market demand (which affects CW^m as well as welfare and profits under duopoly and triopoly). In order to cope with these issues, we introduce a specific competition model where i) firms compete in prices and ii) products are heterogeneous with a variable degree of substitutability. We expect assumptions i) and ii) to

adequately reflect the characteristics of real world markets for pharmaceutical products. The details are summarized in Example 1.

Example 1: We consider a special case of the model presented in Häckner (2000) for the case of n firms where $n \in \{1,2,3\}$. In particular, we suppose the existence of a representative consumer with the utility function

$$U(\mathbf{q},I) = \sum_{i=1}^{n} q_i - \tfrac{1}{2}\left(\sum_{i=1}^{n} (q_i)^2 + 2\delta \sum_{i=1, i\neq j}^{n} q_i q_j \right) + I$$

where q_i denotes firm *i*'s quantity, I represents the consumption of other goods, while δ reflects the degree of substitutability. We restrict the analysis to $\delta \in [0,1)$, i.e. to the case where the products are substitutes. If $\delta = 0$, the products are independent (i.e. firms have monopoly power), whereas for $\delta = 1$, the products are perfect substitutes (i.e. we have perfect competition). By solving the consumer's maximization problem subject to the budget constraint $\sum p_i q_i + p_I I = m$, where p_i denotes the price of product *i*, *m* denotes income and $p_I = 1$, we obtain firm *k*'s inverse demand function, which is

$$p_k = 1 - q_k - \delta \sum_{j=1, j\neq k}^{n} q_j \,.$$

We assume that firms compete in prices and find that firm *k*'s profit-maximizing prices and quantities in equilibrium are given by

$$p_k = \frac{\left[\delta^2\left(n^2-5n+5\right)+3\delta(n-2)+2\right] - \delta\sum_{i=1}^{n}\left[\delta(n-2)+1\right]}{\left[\delta(n-3)+2\right]\left[\delta(2n-3)+2\right]}$$

$$q_k = \frac{\left[\left[\delta^2\left(n^2-5n+5\right)+3\delta(n-2)+2\right] - \delta\sum_{i=1}^{n}\left[\delta(n-2)+1\right]\right]\left[\delta(n-2)+1\right]}{(1-\delta)\left[\delta(n-3)+2\right]\left[\delta(n-1)+1\right]\left[\delta(2n-3)+2\right]}.$$

If we focus on the case under consideration, i.e. on the case of $n \in \{1,2,3\}$, we finally obtain $\pi^m = \frac{1}{4}$, $\pi_o^d = \pi_g^d = (1-\delta)\Big/\left[(2-\delta)^2(1+\delta)\right]$, $\pi_o^t = \pi_g^t = \left(1-\delta^2\right)\Big/\left[4(2\delta+1)\right]$ as well as $CW^m = \frac{1}{8}$, $CW^d = 1\Big/\left[(1+\delta)(-2+\delta)^2\right]$, $CW^t = \left[3(1+\delta)\left(1+3\delta+2\delta^2\right)\right]\Big/\left[8(1+2\delta)^2\right]$. Note that in our model feasible solutions require $t_{g1}^{set}, t_{g2}^{set}, \tilde{t}_{opt}, \gamma_{g1}^{set}, \gamma_{g2}^{set} \in (0,1)$. Under Example 1, this holds for $f_g \in \left[\underline{f}_g, \overline{f}_g\right]$, $\delta \in [\underline{\delta}, 1)$, and $\lambda \in \left[0, \overline{\lambda}\right]$, where $\underline{\delta} \approx 0{,}7478$ and

$$\overline{\lambda} = \left(1792 + 2560\delta - 4736\delta^2 - 9344\delta^3 + 3808\delta^4 + 10816\delta^5 - 1704\delta^6 - 5832\delta^7 \right.$$
$$\left. + 1155\delta^8 + 1554\delta^9 - 699\delta^{10} - 12\delta^{11} + 93\delta^{12} - 30\delta^{13} + 3\delta^{14}\right)\Big/\left(-256 - 1536\delta - 1920\delta^2 \right.$$
$$\left. - 1664\delta^3 + 5280\delta^4 + 5376\delta^5 - 2280\delta^6 - 6024\delta^7 + 1539\delta^8 + 1554\delta^9 - 699\delta^{10}\right.$$

$$-12\delta^{11}+93\delta^{12}-30\delta^{13}+3\delta^{14}\big).$$

Example 1 generates feasible solutions for $\delta\in[\underline{\delta},1)$, i.e. for those cases where the firms' products are sufficiently close substitutes. Our model is therefore particularly relevant for the pharmaceutical industry, because consumers tend to perceive generics as being close (but imperfect) substitutes to the originator's product.

The Effects of an Increase in G_2's Entry Decision Date

The entry decision of the second generic entrant is denoted by λ. We can also directly link this to the actual entry of the second generic, since a later entry decision will lead to a later entry. Therefore, the parameter λ can be interpreted as reflecting competitive pressure from the second generic on the already present firms. We use Example 1 to analyze the impact of λ on $\tilde{t}_{opt}$, which requires studying the influence of λ on γ_{g1}^{set} and γ_{g2}^{set} at first. Our findings are summarized in Lemma 1:

Lemma 1: The settlement surplus in case of two generic entrants, s_1, is strictly decreasing in λ, i.e. we have that $\partial s_1/\partial\lambda<0$. In addition, we find that $\partial\gamma_{g1}^{set}/\partial\lambda=0$ as well as $\partial\gamma_{g2}^{set}/\partial\lambda<0$, which implies that G_1 is not affected, while G_2 strictly challenges less patents if λ marginally increases.
Proof: See Appendix A.

The intuition behind Lemma 1 is based on two arguments: First, the settlement surplus s_1 is decreasing in λ, which might seem somewhat puzzling at first glance, because in general firms are able to reap a higher surplus from a settlement in case that market entry of potential entrants is delayed. Indeed, we find that an increase in λ ceteris paribus shifts the entry decision and hence G_2's actual entry date, $t_{g2}^{set}=\gamma+\tilde{t}+(1-\gamma-\tilde{t})\lambda$, to a later point in time. However, a marginal increase in λ also affects G_2's expected entry date under litigation, which is $t_{g2}^{lit}=\gamma+(1-\gamma)\lambda$. As we have that $\partial t_{g2}^{lit}/\partial\lambda>\partial t_{g2}^{set}/\partial\lambda$, we find that the marginal impact on the entry date is stronger under litigation. Therefore, the surplus decreases in λ. Secondly, it is easy to see that the denominator in $\gamma_{g2}^{set}=1-\big(f_g-(s_1/3)\big)\big/(1-\lambda)\pi_g^t$ is decreasing in λ, which reflects that triopoly profits from entering the market are realized for a shorter period of time. Thus, G_2's critical level of patent strength, γ_{g2}^{set}, is decreasing in λ, because settlement surplus and triopoly profits decrease, making a patent challenge ceteris

paribus less attractive. Based on Lemma 1's results, we can study the overall impact of λ on $\tilde{t}_{opt}$. Our findings are given in Proposition 3:

Proposition 3: Under Example 1, the optimal policy parameter $\tilde{t}_{opt}$ is strictly increasing in λ, i.e. we have that $\partial \tilde{t}_{opt} / \partial \lambda > 0$.
Proof: See Appendix A.

To understand this result, we use Equation (7) to analyze the different effects of a marginal change in λ on $\partial CW^{set} / \partial \tilde{t}$, which determines $\tilde{t}_{opt}$ at $\partial CW^{set} / \partial \tilde{t} = 0$. In general, we can conclude from Lemma 1 and from Equation (7) that an increasing λ influences $\partial CW^{set} / \partial \tilde{t}$ through the incentive- and through the entry delay effect of G_2 only. The corresponding effects for G_1 remain unaffected. G_2's entry delay effect, given in (7) by the expression $\gamma_{g2}^{set}(1-\lambda)\left(CW^t - CW^d\right)$, is decreasing in λ, because we know from Lemma 1 that $\partial \gamma_{g2}^{set} / \partial \lambda < 0$. Hence, we can conclude that the overall entry delay effect of the second generic is lower in case λ increases, which in any case positively affects $\tilde{t}_{opt}$. This result holds in general, i.e. it is independent from Example 1.
In addition, we have to analyze λ's impact on G_2's incentive effect which is given by $\left(\partial \gamma_{g2}^{set} / \partial \tilde{t}\right)\left(1-\gamma_{g2}^{set}-\tilde{t}\right)(1-\lambda)\left(CW^t - CW^d\right)$ in Equation (7). Here, we find that the effect of a marginal increase in λ on this expression is ambiguous: Since we already know that γ_{g2}^{set} is decreasing in λ, we find that λ's marginal impact on the incentive effect is ambiguous, because $(1-\lambda)$ decreases, whereas $\left(1-\gamma_{g2}^{set}-\tilde{t}\right)$ increases. This ambiguity holds in any case, i.e. it is independent from the sign of $\partial \gamma_{g2}^{set} / \partial \tilde{t}\, \partial \lambda$. In order to understand this outcome, we analyze the second generic's actual market entry date for γ_{g2}^{set}, which is given by $t_{g2}^{set}\left(\gamma_{g2}^{set}\right) = \gamma_{g2}^{set} + \tilde{t} + \left(1-\gamma_{g2}^{set}-\tilde{t}\right)\lambda$. As we know from Lemma 1 that γ_{g2}^{set} is decreasing in λ, the overall effect on $t_{g2}^{set}\left(\gamma_{g2}^{set}\right)$ is ambiguous. Hence, at γ_{g2}^{set} it is not clear whether the second generic actually enters earlier or later as a reaction of an increase in λ. This, however, seems to be in sharp contrast to how we previously argued in Lemma 1, where we found that a later entry decision of G_2 corresponds to later market entry and hence to a diminishing critical patent strength γ_{g2}^{set}. The difference results from the different nature of γ: When we described the influence of λ on the range of patents challenged by G_2, t_{g2}^{set} was determined by a randomly drawn and hence exogenous γ, which does *not* depend on λ. On the other hand, if we analyze G_2's incentive effect, we have to take into account that t_{g2}^{set} depends on γ_{g2}^{set}, since the incentive effect is endogenously determined by specific patent strength values.

Overall, we can conclude that the entry delay effect for G_2 is strictly decreasing in λ, while the impact on the incentive effect is ambiguous. Hence, we cannot determine the overall impact on $\tilde{t}_{opt}$ in general. However, under Example 1, we can show that the effect of an increase in λ on the incentive effect is not ambiguous anymore. Instead, we can show that $\partial\left[\left(\partial\gamma_{g2}^{set}/\partial\tilde{t}\right)\left(1-\gamma_{g2}^{set}-\tilde{t}\right)(1-\lambda)\right]/\partial\lambda > 0$,[3] which allows us to conclude that G_2's incentive effect strictly increases in λ. Since we know that the entry delay effect is always strictly decreasing in λ, it is easy to see that $\tilde{t}_{opt}$ is in any case positively affected from a marginal increase in λ. This explains our findings in Proposition 3.

The Effects of an Increase in the Intensity of Competition

The final step of our analysis addresses the influence of δ on the optimal policy. Since δ measures the degree of substitutability between the originator's and the generics' products, it can be interpreted as reflecting the intensity of competition on the market. Again, we study the impact on the critical levels of patent strength, i.e. on γ_{g1}^{set} and γ_{g2}^{set}, at first. Our findings are given in Lemma 2:

Lemma 2: Under Example 1, the critical levels of patent strength are strictly decreasing in δ, i.e. we have that $\partial\gamma_{g1}^{set}/\partial\delta < 0$ as well as $\partial\gamma_{g2}^{set}/\partial\delta < 0$. In addition, it always holds that $\partial\gamma_{g1}^{set}/\partial\tilde{t}\partial\delta > 0$ and $\partial\gamma_{g2}^{set}/\partial\tilde{t}\partial\delta > 0$, i.e. the number of G_1's and G_2's additionally challenged patents resulting from an increase in $\tilde{t}$ is strictly increasing in δ.
Proof: See Appendix A.

Analyzing the intuition for Lemma 2 reveals several insights about the impact of an increase in δ. Since δ can be interpreted as reflecting the intensity of competition, it is easy to see that duopoly profits $\pi_o^d(\delta)$, $\pi_g^d(\delta)$, and triopoly profits $\pi_o^t(\delta)$, $\pi_g^t(\delta)$ decrease, while consumer welfare under duopoly and triopoly, i.e. $CW^d(\delta)$ and $CW^t(\delta)$, increases in δ. If we focus on G_1 at first, we can immediately conclude that due to the decreasing profit under duopoly, the joint settlement surplus, $s_2(\delta)$, is strictly increasing. This effect ceteris paribus has a positive impact on $\gamma_{g1}^{set}(\delta) = 1-\left(f_g-\left(s_2(\delta)/2\right)\right)/\pi_g^d(\delta)$. At the same time, $\gamma_{g1}^{set}(\delta)$ is negatively affected, because $\pi_g^d(\delta)$, i.e. G_1's profit after market entry, is decreasing. Since we know from Lemma 2 that $\partial\gamma_{g1}^{set}/\partial\delta < 0$, we can conclude that the overall impact on $\gamma_{g1}^{set}(\delta)$ is negative. This is not surprising, because G_1 is directly affected from the decrease

[3] The proof has been established in Mathematica. The corresponding code is available from the authors upon request.

of $\pi_g^d(\delta)$, while the increasing settlement surplus is equally shared with the originator. The same argument holds for G_2.

In addition, we know from Lemma 2 that $\partial\gamma_{g1}^{set}/\partial\tilde{t}\partial\delta > 0$, which also results from the decreasing $\pi_g^d(\delta)$. In general, a marginal increase in $\tilde{t}$ affects G_1 in two ways: On the one hand, if $\tilde{t}$ marginally increases, G_1 benefits from a longer period of collusion and hence from higher settlement profits. On the other hand, G_1's market entry is marginally delayed, which reduces the individual profit from entering the market. However, if δ increases, the overall effect is strictly positive: Since $\pi_g^d(\delta)$ decreases, the settlement surplus increases, i.e. collusion is more valuable under a more competitive market. At the same time, the decline of $\pi_g^d(\delta)$ makes an additional delay of market entry less costly for G_1. Hence, G_1's number of additionally challenged patents resulting from a marginal increase of $\tilde{t}$ is strictly increasing in δ. Again, the same logic holds for G_2.

Given the results from Lemma 2, we can finally analyze the overall impact of δ on the optimal policy parameter. The result is summarized in Proposition 4:

Proposition 4: Under Example 1, the optimal policy parameter $\tilde{t}_{opt}$ is strictly increasing in δ, i.e. we have that $\partial\tilde{t}_{opt}/\partial\delta > 0$.

Proof: See Appendix A.

In order to explain the result of Proposition 4, we again use Equation (7). Once more, we distinguish entry delay effect and incentive effect, which determine the impact of our policy parameter on consumer welfare. If we consider G_1 at first, it is easy to see that the difference $CW^d(\delta) - CW^m$ is increasing in δ. Since this expression enters both the incentive- and the entry delay effect of G_1, we ceteris paribus find a countervailing combined effect. Hence, we have to examine the influence of $\gamma_{g1}^{set}(\delta)$ on the incentive- and the entry delay effect. We already know from Lemma 2 that $\partial\gamma_{g1}^{set}/\partial\delta < 0$, which has two effects: At first, G_1's entry delay effect decreases, since the costs of collusion, i.e. $CW^d(\delta) - CW^m$, apply to less already challenged patents. In addition, the incentive effect increases, because the benefit of higher consumer welfare through additional patent challenges is realized for a longer period of time, since G_1's market entry under the marginal settlement takes place earlier, i.e. $t_{g1}^{set}\left(\gamma_{g1}^{set}\right) = \gamma_{g1}^{set} + \tilde{t}$ decreases. Both effects positively influence $\tilde{t}_{opt}$. Moreover, we have found in Lemma 2 that $\partial\gamma_{g1}^{set}/\partial\tilde{t}\partial\delta > 0$, which has an additional positive impact on the incentive effect. Hence, we have that $\tilde{t}_{opt}$ is strictly increasing in δ. For the second generic the same

logic for incentive- and entry delay effect in (7) applies. Our result in Proposition 4 implies that for $\tilde{t}_{opt} > 0$, the competition authorities should grant more collusion on markets that are more competitive, which is not what we would normally expect, since collusion is more harmful on competitive markets. However, in our model, the benefits from additionally challenged patents (the incentive effects) outweigh the costs of more collusion.

The results of our comparative static analysis are summarized in Table 1:

Table 1: Summary of comparative statics results

Marginal Impact on $\tilde{t}_{opt}$	Parameters		
	f_g	λ	δ
Incentive Effect	+	+*	+*
Entry Delay Effect	-	-	-*
Overall Effect	+	+*	+*

"+" and "-" indicate that the absolute values of the effects increase/decrease.
"*" indicates that the effects can be shown under Example 1.

7. Discussion and Conclusion

In the model, we have analyzed the tradeoff between entry delay- and incentive effects in patent settlements between originators and generics. By introducing a policy parameter, we explicitly allow in antitrust law for a longer period of collusion, which negatively affects consumer welfare. However, the provision of more challenging incentives for potentially unjustified (weak) patents has a positive impact on consumer welfare. We show under very general conditions that there exists an optimal specification of the policy parameter, and our key result is that consumer welfare under this optimal policy parameter is higher than under the benchmark case of litigation.

However, it is also a crucial result of our model that, depending on parameter constellations (as, e.g., challenging costs), this optimal policy parameter can be positive or negative. If the optimal policy parameter is positive, limiting the collusion of originators and generics through antitrust law to the expected entry date of the litigation solution would lead to inefficiently small challenging incentives for generics. Hence, a longer collusion period would be beneficial from a consumer welfare perspective. Therefore, another implication of our model is that the consideration of challenging incentives for generics can provide an additional

reason why patent settlements with reverse payments might not harm consumers and are therefore not anticompetitive. In addition, we have shown for this case of $\tilde{t}_{opt} > 0$ that (under certain assumptions) the optimal policy parameter increases with the size of challenging costs, the lag of the second generic's market entry decision, and with the intensity of competition between originators and generics after generic entry.

If, however, the optimal policy parameter $\tilde{t}_{opt}$ is negative (i.e. challenging costs are sufficiently low, $f_g < \underline{f}_g$, see Case 1 in *Fig. 3*), then the expected entry date under litigation would be inefficiently late, i.e. the marginal challenging incentives provided in the litigation benchmark solution would be too large. However, claiming from an antitrust perspective that the rights of the parties to litigate should be limited, might lead to a serious conflict between antitrust and patent law. This possible case of a negative policy parameter shows nonetheless that taking into account challenging incentives can lead to the conclusion that patent settlements without reverse payments can also harm consumers and be anticompetitive.

What conclusions can be drawn from our results? In a comprehensive analysis of the economic literature about patent settlements, Frank/Kerber (2016) have shown that a correct antitrust analysis of the effects of patent settlements requires a deep understanding of the interaction between patent and antitrust law, and therefore an integrated economic analysis of the effects of patent settlements on both innovation and competition. Therefore, the current main focus on price effects is not sufficient and, in addition, the effects on innovation incentives and challenging incentives have to be analyzed. Our model provides an integrated analysis of price effects and challenging incentives and shows that a tradeoff between both can exist, which is relevant for the antitrust assessment of patent settlements. Regarding the analysis of price effects and innovation incentive effects, results of the research by Elhauge/Krüger (2012) and Woodcock (2016a/2016b) seem to suggest that in this case there might be no tradeoff, i.e. an antitrust policy that uses the expected entry under litigation as a benchmark would not lead to inefficiently small innovation incentives.[4] Therefore, innovation incentive arguments might not support claims for allowing longer collusion periods (and therefore reverse payments). Models that try to simultaneously analyze all three effects of antitrust limits for patent settlements on consumer welfare are still missing.

[4] See also Frank/Kerber (2016, pp.12) where a critical analysis of the model of Elhauge/Krüger (2012) can be found, and, from a much broader perspective, the discussion of the proportionality principle in regard to probabilistic patents for innovation incentives in Farrell/Shapiro (2008) and Encaoua/Lefouili (2009).

Another question is whether the results of our model do also hold under less restrictive assumptions. For example, we assumed that i) all patents have the same value, ii) there is a uniform distribution of patent strength in the continuum of all patents, and iii) the challenging costs are the same for all patents. Under more relaxed assumptions, our specific results and the optimal policy parameter would certainly change, but it is not clear why this should change our main results about the existence of an optimal policy parameter and the possibility of a tradeoff with its conclusion that a longer collusion might be justified. Another assumption in our model is that originators and generics know the true patent strength. In previous research, the consequences of wrong and/or asymmetric beliefs about the strength of patents have been analyzed. Allowing for such more realistic assumptions can change the settlement ranges in different ways, and can lead to a number of problems with respect to achieving efficient settlement solutions. Although this makes the antitrust assessment considerably more difficult and would presumably influence the size of the optimal policy parameter, we do not expect our results to change qualitatively. Another specific assumption is the existence of two generic entrants that make sequential entry decisions with an exogenously assumed lag between first and second generic. Since we have shown that the results also hold for one entrant (Appendix B), they do not depend on the specific assumption of two entrants. In addition, they presumably also hold for more than two entrants, as long as a similar structure of sequential entry decisions is assumed. However, we do not model the multiple challenger problem, i.e. that there might be several generic entrants that simultaneously decide on challenging patents with the ensuing public good problem. So far, we are not aware of a model that includes this public good problem in the economic analysis of the antitrust treatment of patent settlements.[5] It is clear that a more explicit analysis of the effects of the interaction and competition between potential generic entrants is one of the important gaps in previous research. Therefore, there are still a large number of important questions for future economic research.

What conclusions can be drawn for the initial question of how to deal with the weak patent problem? Taking challenging incentives into account in the antitrust assessment does not change the necessity of a very critical antitrust scrutiny of patent settlements with reverse payments for eliminating an easy way for originators to protect potentially unjustified and weak patents that can harm consumers. The consideration of challenging incentives can help

[5] Some authors have discussed scenarios of multiple generic entries in specific frameworks. However, they have not analyzed the public good problem (Edlin et al. (2015), Kobayashi et al. (2015)).

to optimize the antitrust assessment of patent settlements, but it is also clear that this can only contribute to a limited extent to the solution of the weak patent problem. Therefore, it is still necessary to search for other solutions as part of the general problem of the optimal patent system's design. Important proposals about improving patent examination procedures in patent offices, facilitating and strengthening of patent opposition and patent litigation procedures, e.g. by joint challenges, and promoting subsidization of patent challenges can be found in Miller (2004), Farrell/Shapiro (2008), and Encaoua/Lefouili (2009).

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Appendix A: Proofs

Proof of Proposition 1:

Given Equation (6) we find that

$$(11) \qquad CW^{set}\left(\tilde{t}_{opt}\right)-CW^{set}\left(0\right)=$$
$$\left[\left(CW^{d}-CW^{t}\right)f_g\left(\pi_g^{d}\right)^2-3\left(1-\lambda\right)\pi_g^{t}\left(2\left(CW^{t}-CW^{d}\right)f_g\left(\pi_g^{d}\right)^2+\left(\varphi_2\left(CW^{d}-CW^{m}\right)f_g\right.\right.$$
$$\left.\left.+2\pi_g^{d}\left(\left(CW^{d}-CW^{m}\right)f_g+\left(CW^{m}-CW^{t}\left(1-\lambda\right)-CW^{d}\lambda\right)\pi_g^{d}\right)\right)\pi_g^{t}\right)\Bigg]^2\Bigg/$$
$$\left[2\left(1-\lambda\right)\left(\pi_g^{d}\right)^2\left(\pi_g^{t}\right)^2\left(4\left(\varphi_1\right)^2\left(CW^{t}-CW^{d}\right)\left(\pi_g^{d}\right)^2+24\varphi_1\left(CW^{t}-CW^{d}\right)\left(1-\lambda\right)\left(\pi_g^{d}\right)^2\pi_g^{t}\right.\right.$$
$$\left.\left.+9\varphi_2\left(CW^{d}-CW^{m}\right)\left(1-\lambda\right)\left(\varphi_2+4\pi_g^{d}\right)\left(\pi_g^{t}\right)^2\right)\right].$$

Since we have that $CW^{t}>CW^{d}>CW^{m}$, $\lambda\in\left(0,1\right)$ as well as $\varphi_1,\varphi_2,\pi_g^{t}>0$, we can show that $CW^{set}\left(\tilde{t}_{opt}\right)-CW^{set}\left(0\right)\geq 0$, because the single-rooted[6] numerator in (11) is nonnegative, while the denominator is strictly positive. Since for $\tilde{t}_{opt}=0$ it obviously holds that $CW^{set}\left(\tilde{t}_{opt}\right)=CW^{set}\left(0\right)$, we can conclude that $CW^{set}\left(\tilde{t}_{opt}\right)-CW^{set}\left(0\right)>0$ for $\tilde{t}_{opt}\neq 0$.

Proof of Proposition 2:

Using Equation (10) we can show that for $CW^{t}>CW^{d}>CW^{m}$, $\lambda\in\left[0,1\right)$ as well as $\varphi_1,\varphi_2,\pi_g^{d},\pi_g^{t}>0$ it holds that

$$\frac{\partial\tilde{t}_{opt}}{\partial f_g}=\frac{-\frac{\left(CW^{d}-CW^{m}\right)\left(\varphi_2+2\pi_g^{d}\right)}{2\left(\pi_g^{d}\right)^2}-\frac{\varphi_1\left(CW^{t}-CW^{d}\right)}{3\left(1-\lambda\right)\left(\pi_g^{t}\right)^2}-\frac{CW^{t}-CW^{d}}{\pi_g^{t}}}{-\frac{\varphi_2\left(CW^{d}-CW^{m}\right)\left(\varphi_2+4\pi_g^{d}\right)}{4\left(\pi_g^{d}\right)^2}-\frac{\left(\varphi_1\right)^2\left(CW^{t}-CW^{d}\right)}{9\left(1-\lambda\right)\left(\pi_g^{t}\right)^2}-\frac{2\varphi_1\left(CW^{t}-CW^{d}\right)}{3\pi_g^{t}}}>0.$$

Proof of Lemma 1:

Since $\pi_o^{d}+\pi_g^{d}>\pi_o^{t}+2\pi_g^{t}$ and $\tilde{t}>0$, it is easy to show that

$$\partial s_1/\partial\lambda=\tilde{t}\left(-\left(\pi_o^{d}+\pi_g^{d}\right)+\left(\pi_o^{t}+2\pi_g^{t}\right)\right)<0.$$

[6] The proof has been established in Mathematica. The corresponding code is available from the authors upon request.

In addition, we see that λ does not enter Equations (3) and (4), so we have that $\partial\gamma_{g1}^{set}/\partial\lambda = 0$. Moreover, we know that $\partial\gamma_{g2}^{set}$ is given by Equation (5). Taking the derivative with respect to λ yields

$$\frac{\partial\gamma_{g2}^{set}}{\partial\lambda} = -\frac{\left[-\frac{1}{3}\frac{\partial s_1}{\partial\lambda}(1-\lambda)\pi_g^t - \left(f_g - \frac{s_1}{3}\right)\left(-\pi_g^t\right)\right]}{(1-\lambda)^2\left(\pi_g^t\right)^2},$$

which is strictly smaller than zero, because $\pi_g^t > 0$, $\lambda \in (0,1)$, $f_g - \frac{s_1}{3} > 0$ and $\frac{\partial s_1}{\partial\lambda} < 0$.

Proof of Proposition 3:

By plugging Example 1's expressions for profits and welfare into Equation (10) we obtain $\tilde{t}_{opt}(\delta)$, which is given by

(12)
$$\begin{aligned}\tilde{t}_{opt}(\delta) = [&24(-2+\delta)^2(1+\delta)(-24(-1+\delta)^2(2+\delta-\delta^2)^4(2+\delta(4+3\delta))\\
&-(-2+\delta)^2(1+\delta)(1+2\delta)(-320+\delta(-896+\delta(-656+3\delta(176+\delta(404\\
&+\delta(64+\delta(-99+\delta(-43+\delta(22+(-5+\delta)(-2+\delta)\delta)))))))) f_g\\
&+(24(-2+\delta)^2(-1+\delta)^2(1+\delta)^3(12+\delta(24+\delta(9+\delta(-25-8\delta+6\delta^2))))+(1+2\delta)\\
&(-1792+\delta(-4608+\delta(-384+\delta(9088+3\delta(2176+\delta(-2688+\delta(-984\\
&+\delta(296+\delta(1+\delta)(225+\delta(-91+\delta(-46+\delta(42+(-11+\delta)\delta)))))))))) f_g)\lambda\\
&-24(-2+\delta)^2(-1+\delta^2)^3(-4+3\delta(-4-5\delta+\delta^3))\lambda^2)]/\\
&[-(-2+\delta)^4(1+\delta)^2(3776+\delta(5376+\delta(-11472+\delta(-25616+3\delta(-4+\delta(9368\\
&+\delta(3159+\delta(-3667+3\delta(-384+\delta(246+\delta(13+\delta(-13+2\delta)))))))))))+\\
&(-2+\delta)^2(1+\delta)(21248+\delta(25600+\delta(-91008+\delta\\
&(-172160+\delta(102080+3\delta(107136+\delta(-11720+\delta(-83224+\delta(-1709+3\delta(10824\\
&+\delta(-701+\delta(-1942+\delta(407+\delta(52+\delta(-19+2\delta)))))))))))))\lambda-64(-1+\delta)^3(-4\\
&+3\delta(-4-5\delta+\delta^3))(4+\delta(-4+3(-3+\delta)\delta(1+\delta)))(20+\delta(28+3(-3+\delta)\delta(1+\delta)))\lambda^2].\end{aligned}$$

Based on $\tilde{t}_{opt}(\delta)$ we compute $\partial\tilde{t}_{opt}/\partial\lambda$. We omit the details, because the corresponding expression is very complex. Then we can show that for $t_{g1}^{set}, t_{g2}^{set}, \tilde{t}_{opt}, \gamma_{g1}^{set}, \gamma_{g2}^{set} \in (0,1)$ as well as for $f_g \in \left[\underline{f}_g, \overline{f}_g\right]$, $\delta \in [\underline{\delta}, 1)$, and $\lambda \in \left[0, \overline{\lambda}\right]$ we have that $\partial\tilde{t}_{opt}/\partial\lambda > 0$.[7]

Proof of Lemma 2:

Using Example 1's expressions for firms' profits in Equations (4) and (5) we know that

[7] The proof has been established in Mathematica. The corresponding code is available from the authors upon request.

$$\frac{\partial \gamma_{g1}^{set}}{\partial \delta} = \frac{(-2+\delta)\left(1+(-1+\delta)\delta\right)\left(8 f_g - \tilde{t}\right)}{4(-1+\delta)^2},$$

$$\frac{\partial \gamma_{g2}^{set}}{\partial \delta} = \frac{24\varphi_3 f_g - 2\left(\varphi_3 + 8(-1+\delta)^2\left(1+\delta+3\delta^2\right)\lambda\right)\tilde{t}}{3(-2+\delta)^3(-1+\delta)^2(1+\delta)^3(-1+\delta)},$$

where $\varphi_3 = (-2+\delta)^3(1+\delta)\left(1+\delta+\delta^2\right)$. Then we find that for $t_{g1}^{set}, t_{g2}^{set}, \tilde{t}, \gamma_{g1}^{set}, \gamma_{g2}^{set} \in (0,1)$ as well as for $f_g \in \left[\underline{f}_g, \overline{f}_g\right]$, $\delta \in [\underline{\delta}, 1)$, and $\lambda \in (0, \overline{\lambda})$ we have that $\partial \gamma_{g1}^{set} / \partial \tilde{t} \partial \delta > 0$ and $\partial \gamma_{g2}^{set} / \partial \tilde{t} \partial \delta > 0$.

Moreover, we know from (8) and (9) that under Example 1 we have that

$$\frac{\partial \gamma_{g1}^{set}}{\partial \tilde{t} \partial \delta} = \frac{1}{4}\left(1 - \delta + \frac{1}{(-1+\delta)^2}\right),$$

$$\frac{\partial \gamma_{g2}^{set}}{\partial \tilde{t} \partial \delta} = -\frac{2\varphi_3 + 16(-1+\delta)^2\left(1+\delta+3\delta^2\right)\lambda}{3(-2+\delta)^3(-1+\delta)^2(1+\delta)^3(-1+\lambda)}.$$

We can show that for $\delta \in [0,1)$ and $\lambda \in (0,1)$ it always holds that $\partial \gamma_{g1}^{set} / \partial \tilde{t} \partial \delta > 0$ and $\partial \gamma_{g2}^{set} / \partial \tilde{t} \partial \delta > 0$.

Proof of Proposition 4:

We already know that under Example 1 the optimal policy parameter $\tilde{t}_{opt}(\delta)$ is given by Equation (12). Based on (12) we compute $\partial \tilde{t}_{opt} / \partial \delta$. Again, the details are omitted due the output's complexity. We can show that for $t_{g1}^{set}, t_{g2}^{set}, \tilde{t}_{opt}, \gamma_{g1}^{set}, \gamma_{g2}^{set} \in (0,1)$ as well as for $f_g \in \left[\underline{f}_g, \overline{f}_g\right]$, $\delta \in [\underline{\delta}, 1)$, and $\lambda \in (0, \overline{\lambda})$ it holds that $\partial \tilde{t}_{opt} / \partial \lambda > 0$.

Appendix B: Optimal policy in case of one generic entrant

The case of one generic entrant is equivalent to the special case of our model where $\gamma_{g2}^{set} = 0$. Hence, we can immediately conclude from Equation (6) that consumer welfare is given by

$$CW^{set} = \left[(1-\tilde{t})\gamma_{g1}^{set}(\tilde{t}) - \frac{\gamma_{g1}^{set}(\tilde{t})^2}{2}\right]\left(CW^d - CW^m\right) + CW^m.$$

Maximizing CW^{set} with respect to $\tilde{t}$ yields

$$\frac{\partial CW^{set}}{\partial \tilde{t}} = \underbrace{\frac{\partial \gamma_{g1}^{set}}{\partial \tilde{t}}\left(1-\gamma_{g1}^{set}-\tilde{t}\right)\left(CW^{d}-CW^{m}\right)}_{\text{Incentive Effect - } G_1} - \underbrace{\gamma_{g1}^{set}\left(CW^{d}-CW^{m}\right)}_{\text{Entry Delay Effect - } G_1},$$

so that by respecting (8) we find that

$$\tilde{t}_{opt} = \frac{2\varphi_2 f_g + 4 f_g \pi_g^d - 4\left(\pi_g^d\right)^2}{\left(\varphi_2\right)^2 + 4\varphi_2 \pi_g^d}.$$

Comparing consumer welfare under litigation and consumer welfare under the optimal policy yields

$$CW^{set}\left(\tilde{t}_{opt}\right) - CW^{set}\left(0\right) = \frac{\left(CW^{d}-CW^{m}\right)\left(\varphi_2 f_g + 2\left(f_g - \pi_g^d\right)\pi_g^d\right)^2}{2\varphi_2\left(\pi_g^d\right)^2\left(\varphi_2 + 4\pi_g^d\right)},$$

for which we can show that $CW^{set}\left(\tilde{t}_{opt}\right) - CW^{set}\left(0\right) \geq 0$, because $CW^{d} > CW^{m}$ and $\varphi_2, \pi_g^d > 0.$

Essay 4:
Patent Settlements in Europe and the Lundbeck Case: A Competition Law and Economics Perspective

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Mimeo 2016.

Patent Settlements in Europe and the Lundbeck Case: A Competition Law and Economics Perspective

Jonas Severin Frank*

Abstract

The paper studies the Lundbeck patent settlement antitrust case of the European Commission from an economic perspective. The Commission concludes that the agreements in Lundbeck involving reverse payments from the originator to generics have violated competition law. The paper shows that this decision is the correct one. More broadly the paper analyzes problem areas of patent settlement assessment in Europe. It assesses what we can learn from the U.S. patent settlement debate with particular focus on the differences in regulatory frameworks of the pharmaceutical sector which are relevant for patent settlement assessment. The recommendation is presented that, instead of taking into account the wide range of factors and effects which are important for the correct assessment of these agreements, we should rather aim at a more pragmatic approach. The paper suggests that a presumption of the illegality of reverse payments in patent settlements and a safe harbor rule for agreements without reverse payments can be a feasible approach.

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1. Introduction

In Europe, the number of patent settlement agreements between originator and generic firms in the pharmaceutical sector has surged during the last decade. At the same time the European Commission (EC) has increasingly raised antitrust concerns regarding a significant share of these agreements (European Commission 2015a). Patent Settlement agreements have been accused to delay generic market entry by using value transfers from the originator to the generic to the detriment of consumers. If the validity of a patent is questionable the patent holder has an interest to block generic entry and cease patent litigation while a generic might accept a compensation for delaying market entry and ending patent challenges. In the pharmaceutical sector, generic and brand products are close substitutes. Thus, the effect on consumer welfare through price effects from generic entry can be considerable. Launch prices of generics are on average 25% lower than those of brand products with existing monopoly protection. Two years after launch the prices of generics are 40% lower than the originators former brand prices (European Commission 2009, pp. 8). Since after generic entry drug prices drop significantly, both a compensation payment from the originator to the generic as well as a delayed entry by the generics can be beneficial for the parties. These types of agreements are referred to as pay-for-delay settlements since they usually go along with a commitment of the generic not to challenge the validity of the patent for the duration of the agreement. In the pharmaceutical sector inquiry, the European Commission monitored these problematic agreements and started several proceedings against originator and generic firms.[1] This is the background of the recent Lundbeck decision of the European Commission (Case at.39226 – Lundbeck, pp. 221 at paras. 643, 644).

On 19 June 2013, the European Commission DG Competition decided that the Danish originator firm Lundbeck and several generics have been violating EU antitrust rules by a "restriction by object", in particular Article 101 TFEU and Article 53 of the EEA Agreement, in six problematic agreements between 2002 and 2003. On 8 September 2016, the General Court dismissed a motion by the generic firm Arrow to in part annul the Commission's decision (General Court Case T-467/13). The core question the Commission has dealt with is, whether entry restrictions for generics included in the agreements lay within or outside the scope of patent protection of Lundbeck for products involved. The Lundbeck Case represents an important milestone in the application of EU antitrust rules for patent settlements. It can be seen not only as a continuation but as a refinement of the Commission's assessment of these types of agreements. Antitrust action has also been taken in the U.S. where the U.S. Supreme Court has decided on the matter of patent settlements in its Actavis decision. The ruling in Actavis, although not specifying an assessment scheme for patent settlements, made it clear that agreements between patent holders and generics are subject to antitrust scrutiny (570 U. S. ____ (2013) FTC v. Actavis, Inc). Previously the U.S. Federal Trade Commission, the U.S. Department of Justice as well as courts had dealt with various patent settlement agreements with partly deviating standpoints (ibid., pp. 2). The review of patent settlements has also been much discussed in economic literature. Although economists and legal scholars agree that value transfers from the originator to the generic can delay market entry which likely results in higher prices, it can also be shown that complex interaction effects are relevant. Besides price effects because of later generic entry into the market, also effects on innovation and effects on incentives to challenge patents are important for consumer welfare. This makes the analysis of these types of agreements particularly complex. Also, it needs to be taken into account that such analyses are prone to errors and error costs. Before this background the paper studies if the decision of the European Commission in Lundbeck is correct and how this relates to broader problem areas in patent settlement assessment and

[1] Prominent cases in which the Commission took action are Citalopram (European Commission 2013b), Perindopril (European Commission 2014a), Fetanyl (European Commission 2013a) and Modafinil (European Commission 2011).

also to policies in the U.S. Based on economic reasoning policy recommendations shall be derived regarding an appropriate way to assess patent settlements.

The paper is structured as follows: First, an overview is given about the most important economic reasoning in the patent settlement debate. Subsequently the patent settlement policy in Europe is explained. In the main part the Commission's Lundbeck case is analyzed, followed by a critical economic assessment of general problem areas in the assessment of patent settlements in the EU. The next section focuses on the question what we can learn from the U.S. patent settlement debate with particular focus on the differences in the institutional frameworks. The following part addresses the question, how good rules for patent settlement assessment could look like and which policy implications can be drawn. This section is followed by the conclusion.

2. Economic reasoning in the patent settlements debate

To analyze how the Commission assesses the Lundbeck agreements from an economic perspective first this section shall give an overview about the economic arguments brought forward in the patent settlement debate. In the economic literature price effects of patent settlements have been approached from multiple perspectives. Specifically, a reverse payment from the originator to the generic has the ability to delay market entry and thus harm consumers through longer periods of monopoly pricing instead of competition. This is shown by basic models which have been widely accepted (e.g. Shapiro 2003, Elhauge/Krüger 2012).

Both economic and legal scholars have extensively studied the issue of patent settlements. It is important to note that the entire problem of patent settlements relates strongly to the issue of weak or probabilistic patents which can be regarded as a fundamental problem of the patent system but also as a background problem of the patent settlements discussion (Ayres/Klemperer 1999, Farrell/Shapiro 2008). On the one hand, there is strong evidence that many patents are found invalid in courts (Lemley/Shapiro 2005) while on the other hand there might be justifications from a cost efficiency perspective that patent offices are "rationally ignorant" in granting too many patents instead of thorough investigations into patents with limited value (Lemley 2001). However, it is also clear that society has an interest to remove invalid intellectual property rights to prevent unjustified monopolies which however is costly both for society and for private firms. The removal of invalid intellectual property rights can be enforced privately through patent challenges or directly by the state (e.g. through re-examinations in patent offices). For private enforcement, the literature discusses procedural solutions (Fischmann 2016, pp. 480) or a subsidy program to incentivize private patent challenges (Miller 2004). Böhme et al. (2016) find that allowing collusion in patent settlements for incentivizing patent challenges can increase consumer welfare.

The widely-accepted consumer welfare standard for patent settlement assessment, proposed by Shapiro 2003, entitles consumers to the same level of welfare in a settlement agreement than in a scenario where the patents validity is tested in court (Shapiro 2003, p. 396). Thus, a test of patent validity is regarded as the normative consumer welfare benchmark from which an expected entry under litigation can be derived. Restrictions in a settlement agreement should not, according to this standard, make consumers worse off. Economic scholars have developed settlement models which take into account this basic rational in which they assign a certain strength to patents derived from the probability that the patent is valid. They model firms which agree on generic entry dates while sharing profits through reverse payments taking into account the strength of the patent as well as their costs to litigate the patent in court (e.g. Shapiro 2003, Schildkraut 2004, Willig/Bigelow 2004, Elhauge/Krüger 2012, Gratz 2012). From the basic model, it is clear that reverse payments have the ability to shift the generic entry date to a later point in time.

The basic patent settlement model involves an originator and one generic (e.g. Frank/Kerber 2016, pp. 7). The originator holds a patent with a specified and known patent strength. Both firms agree on a generic entry date and on a reverse payment from the originator to the generic as long as this is profitable for them compared to the outside option which would be to litigate the patent. Litigation in the basic models includes litigation costs. It can be easily shown that the reverse payment induces the generic to accept a later market entry (and larger reverse payments lead to even later entry dates). Both parties have a strong incentive to use a reverse payment to share monopoly profits and avoid competing early with each other. The optimal outcome for the parties of such an agreement would be to maximize joint profits by restricting generic entry until the end of the patent term while sharing monopoly profits through reverse payments. Specifically, if the reverse payment is larger than the originators litigation costs generic entry is delayed compared to what would be expected under litigation. The reason for that result is that the effect of a settlement with a relatively small reverse payment could be to just prevent litigation costs for the originator but not to delay entry. However, if the reverse payment is larger than these litigation costs the entry delay effect applies. Consumers are worse off since prices remain on a higher level for a longer duration. Based on the welfare benchmark of Shapiro the main conclusion from the basic model is that reverse payments and a restriction of generic entry are generally problematic in patent settlements with weak patents. This is because they lead to later generic market entry and higher prices. The loss in consumer welfare is more problematic the higher the reverse payment or the weaker the patent is, since a weaker patent should correspond to earlier market entry and a larger reverse payment induces generics to accept later entry dates.

The basic model has been extended to more realistic bargaining conditions taking into account different effects which might be important for the assessment whether reverse payments are pro- or anticompetitive. Depending on the specific situations these effects can lead to generic entry dates deviating from results of the basic model. Therefore, not every patent settlement with a reverse payment is problematic and not every patent settlement without a reverse payment is unproblematic. Economic and legal scholars have used different variants of these models or reasoning to assess patent settlements as leading to generic entry dates before the expected entry under litigation (procompetitive) or generic entry dates after the expected entry under litigation (anticompetitive) (Shapiro 2003, Janis/Hovenkamp/Lemley 2003, Willig/Bigelow 2004, Schildkraut 2004, Bulow 2004, Addanki/Daskin 2009, Dickey et al. 2010, Elhauge/Krüger 2012). Willig/Bigelow (2004, pp. 667) analyze effects of asymmetric information about market value and high litigation costs arguing that there exist patent settlements where a reverse payment is necessary for reaching a procompetitive agreement in case only the originator has knowledge about the value of the respective market. There are possible agreements specifying generic market entries before expected entry under litigation, which require that the generic is compensated for uncertainty about the future market value. More generally Dickey et al. (2010) argue that in case originators or generics have specific information which the other party is unaware of, procompetitive settlements can be feasible (pp. 383). Different beliefs about the patent strength influence the parties expected litigation profits, meaning that the profitability of their outside option compared to the settlement is influenced as well. In case e.g. the originator falsely beliefs the patent is rather weak, it would accept a relatively early generic market entry. Depending on the constellation of different beliefs, the settlement range (combinations of generic entry dates and reverse payments) can be broader or narrower. The use of reverse payments can make it feasible for parties to reach an agreement and bridge existing incentive gaps (Willig/Bigelow 2004, pp. 672, Dickey et al. 2010, pp. 395). It is possible to identify settlements of this kind with a reverse payment larger than litigation costs which are beneficial for consumers compared to the expected consumer welfare under litigation. In case one or both parties are optimistic regarding their probability of winning in litigation, settlements without a reverse payment might not be possible. However, if reverse payments are allowed then the optimism problem can be overcome since the originator can profitably pay an amount which is

acceptable for the generic.[2] There are settlements including such payments which are procompetitive.[3] If a non-litigant is expected to enter at a certain date (which would lead to zero profits for the parties) this de-facto diminishes the patent duration. It also influences which settlements are feasible. Even if symmetric information is assumed and litigation costs are absent (so also risk neutrality is assumed) it might not be possible to reach a procompetitive settlement without a reverse payment.[4] Schildkraut (2004, pp. 1059) argues that if the incumbent is risk-averse with respect to the risk of losing at trial, it could accept also a slightly earlier entry of the generic than under litigation. If at the same time the generic is "cash-strapped", meaning it would demand an even earlier entry, there could not be an agreement without a reverse payment. A similar argument is possible for the situation of a risk-averse originator and a generic which has misplaced optimism. Also, here a reverse payment could enable settlements which lead to earlier entry than under litigation since the originator is willing to accept a slightly earlier entry to avoid to risk of losing at trial (ibid., pp. 1064). Gratz (2012) shows in a model of patent settlements between one originator and one generic where litigation and settlement costs are taken into account that the question whether reverse payments should be prohibited depends also on risk aversion and optimism.[5] Dickey et al. (2010) argue that litigation costs enable settlements which lead to earlier entry than under litigation. However, it is also argued that although the range of possible settlements includes procompetitive settlements it is not clear how likely it is that these are actually reached in negotiations (p. 380). Similarly, Dickey et al. (2010) argue that risk aversion increases litigation costs and thus has similar effects for making procompetitive settlements possible (pp. 381). These different economic arguments clearly show that bargaining between settlement parties is complex and the models can give clear justifications for reverse payments being procompetitive in specific situations.

Besides price effects, it is clear from an economic perspective that two other types of effects are relevant for patent settlement assessment which are innovation incentives effects and challenging incentives effects. Since patent settlements are directly linked to the incentive mechanism and enforcement of patents they have effects on innovation incentives. Although the question how the weak patent notion relates to innovation incentives is complex, it is clear that innovation incentives can be too low but also too high in patent settlements. Authors have discussed the influence of patent settlements on innovation

[2] This is because one day of monopoly is worth more to the incumbent than one day of duopoly for the generic which gives leeway for this payment (Schildkraut 2004, p. 1062). Dickey et al (2010) similarly argue that in case the generic is too optimistic there can be settlements which are procompetitive but are not feasible. At the same time in case the originator is overoptimistic this would decrease the range of procompetitive settlements. So, Dickey et al. make the point that there are procompetitive settlements and reverse payments might be necessary to achieve them. The idea here is that the reverse payment from a theoretical standpoint makes later entries acceptable for generics but there is a range of settlements where this is better than under litigation (pp. 394).

[3] E.g. if both parties have different but also biased assessments of success in patent litigation, a reverse payment could even enable procompetitive settlements compared to litigation without any litigation costs or risk aversion. This is because the patent holder could be rather pessimistic about the winning probability at trial and thus accept that a generic enters earlier than under the true litigation solution. Depending on the generic's assessment of success an agreement might not be reached without reverse payment. Such a payment can bridge this assessment gap and lead to procompetitive solutions. (Willig/Bigelow 2004, p. 673)

[4] Both parties have, without a payment, different minimum demands for entry dates compared to litigation. This is because for the parties the litigation solutions yield different outcomes taking into account monopoly -, duopoly - and zero profit periods. For the originator, a generic entry date before the expected litigation entry might be feasible including a reverse payment since the non-litigant's entry in the originators calculus diminished the patent life anyway (Willig/Bigelow 2004, pp. 673).

[5] E.g. in case generics have a weaker bargaining position in settlement negotiations through risk aversion or originator optimism, she suggests that reverse payments should not be generally banned to improve incentives for challenging patents.

incentives, but conclusions are not so clear.[6] Similar to the economics of patents, optimal innovation incentives in patent settlements mean that there exist tradeoffs regarding price effects (Frank/Kerber 2016)[7]. Also, relevant for patent settlement assessment are effects of the agreements on the incentives to challenge weak patents. On the one hand society benefits from earlier generic market entry as a result of a patent challenge, while on the other hand generics need incentive for costly patent challenges.[8] Economists have modelled tradeoffs between negative price effects though collusion in settlement agreements and beneficial effects for incentivizing the challenging of more patents. This can give justifications for granting the firms some leeway for collusion which however depends on assumptions and parameter constellations (Gratz 2012, Böhme et al. 2016).[9] It is also problematic that challenging incentives not only relate to the present case but to potentially challenged patents in the future. Economic theory suggests that in case weak patents are concerned generics have relatively high incentives to challenge even without collusive agreements (Böhme et al. 2016). However, challenging patents might be a public good problem if multiple generic challengers exist (Edlin et al. 2015, pp. 19). Although the exact interplay of challenging incentive and innovation incentive effects with price effects in patent settlements is not well understood, all three effects are relevant for their assessment (Frank/Kerber 2016). Since until now there is no integrated economic model of reverse payment patent settlements taking into account all these different effects, it seems rather unlikely at the moment that authorities would be able to efficiently carry out such kinds of integrated analyses.

It is very important to note that the complex bargaining situation of parties in patent settlements also depends on the institutional framework they are established in (Frank/Kerber 2013). Three institutional pillars are relevant for settlement agreements in the pharmaceutical sector which are patent law, marketing approval regulations and pricing and reimbursement schemes. These institutional pillars, respectively and in relation to each other, influence the bargaining power of parties and whether pro- or anticompetitive settlements are concluded. For example, regulatory agencies require originator firms to conduct clinical trials and go through approval proceedings for new drugs. At the same time, these regulatory agencies grant specific intellectual property rights (data protection, marketing exclusivity) as part of the regulatory process for originators. In bargaining situations in patent settlements, and also for their antitrust assessment, it is crucial whether a generic would be able to directly enter the market in case the patent is invalidated, or whether entry would not be possible because of existing regulatory barriers. At the same time, regulatory marketing exclusivity for generic patent challengers like in the US might make it much easier to agree on patent settlements.[10] It is evident that the regulatory framework of the pharmaceutical sector is intentionally designed to influence competition and innovation. The interconnection between patent law and regulatory approval also becomes clear when observing that the

[6] Elhauge/Krüger (2012) and Woodock (2016a/2016b) include an innovation incentive perspective in their analysis of patent settlements. They are skeptical about patent settlements with and without reverse payments, however based on different reasoning. Elhauge/Krüger use the concept of probabilistic patents and transfer it to a normative criterion for innovation incentives.

[7] Frank/Kerber (2016) emphasize that innovation incentives are based on the entire patent duration not only the remaining patent duration after the conclusion of a settlement agreement. Accordingly, the point in time of the conclusion of the settlement agreement is important for its assessment in terms of innovation effects if weak patents are involved (pp.12).

[8] The discussion around challenging incentives of patents and the effects on the assessment of patent settlements can also be found amongst legal scholars like Farrell/Merges (2004, pp. 952) or Hemphill (2006, pp. 150).

[9] Including challenging incentives in patent settlements does not always mean that more collusion, thus later generic market entry than under litigation, should be allowed. On the contrary an optimal solution might still require an earlier market entry than under litigation. It is clear from the models however that challenging incentives are an argument for allowing later market entry in general (Böhme et al. 2016).

[10] This refers to regulation in the U.S. which grants 180 days of marketing exclusivity for the first generic patent challenger and its implications (Carrier 2009, pp. 70).

status of the patent is, in some jurisdictions, important for general marketing approval.[11] Pharmaceutical pricing and reimbursement schemes influence price competition as well as distribution after generic market entry. This refers to demand and supply side measures to keep drug prices under control (e.g. direct price control for reimbursement drugs, budget control, mandatory substitution of the cheapest drug and financial incentives for doctors or pharmacies for prescribing generic drugs). There is also a strong influence of health insurers on drug pricing through negotiations, tendering or legal possibilities to directly control the reimbursement of drugs (European Commission 2009, pp. 132). This is crucial for estimating prospective profits and influences the parties' bargaining position in settlements. The importance of taking into account also the regulatory framework and the interconnection of the three different pillars shows the complexity of the task to thoroughly assess whether patent settlements are pro- or anticompetitive. It should be noted that all institutions are highly relevant but also very different in different countries which will be further discussed at a later point.

3. Patent settlement policy in the EU

Lundbeck and other prominent cases reflect the importance of the European approach towards patent settlements. Already earlier the Commission has looked critically at patent settlements and implemented policies. In its pharmaceutical sector inquiry between 2000-2008 (European Commission 2009) and several following patent settlement monitoring rounds between 2008 and 2014 (European Commission 2015a) the Commission identified groups of problematic agreements which led to an adoption of the European Commission Guidelines on the application of Article 101 to technology transfer agreements[12]. The guidelines deal with the question whether or not such types of agreements should be exempted from the prohibition of cartels (European Commission 2014c). However, the Guidelines do not specify a clear assessment scheme for patent settlements which means that the Commission's approach to the matter can be best reviewed by looking at a specific case. Also in the Lundbeck Case the Commission did not apply the Guidelines directly since no technology transfer between the parties was taking place. However, it will be shown that the basic principles for an assessment of patent settlements from the guidelines are consistent also with the Lundbeck decision.

The more concrete assessment of patent settlements initially took course in the EU Commission's pharmaceutical sector inquiry. The sector inquiry categorized patent settlements and revealed that particularly agreements with a value transfer from the originator to the generic accompanied by a restricted generic market entry are problematic (European Commission 2009, pp. 268). Competition concerns are raised especially if a patent challenge is prevented (e.g. by including a no-challenge clause), generic access delayed and at the same time there exists no justification for the reverse payment (European Commission 2015a, pp. 2). The Commission classified patent settlements into 4 categories. Firstly, agreements with and without generic entry restrictions were distinguished. Regarding those with an entry restriction the Commission separated further between agreements with and without reverse value transfers (European Commission 2009, p 270).[13] Whereas the Commission sees agreements without an entry restriction as rather unproblematic, especially the combination of an entry restriction and a reverse value transfer is seen as likely violating Article 101 TFEU which prohibits agreements "which have as their object or effect the prevention, restriction or distortion of competition within the internal market" inter alia

[11] About the topic of patent linkage in the U.S. see Rius Sanjuan 2006, pp. 2.
[12] Hereinafter abbreviated as "European Commission Technology Transfer Guidelines".
[13] During the pharmaceutical sector inquiry from 2000-2008 the Commission monitored 207 settlement agreements. Approximately 50% of these settlements restricted generic entry. 45 settlements amongst those moreover included a reverse value transfer (European Commission 2009, pp. 277). From 2000 to 2014 the shares of particularly problematic settlements with entry restriction and a reverse value transfer fluctuated between 3 and 22% - see Appendix A (European Commission 2015a, p. 9.)

through limiting or controlling market conduct or market sharing (Article 101 (1) TFEU). At the same time, agreements without a value transfer but with a generic entry restriction are not immune from antitrust scrutiny especially in cases where the patent was mistakenly granted or the agreements are outside of the exclusionary scope of the patent. The Commission notes that such agreements might also raise antitrust concerns (OECD 2014, p. 8). In the EU, agreements falling in the scope of Article 101 TFEU might be exempted from prohibition in case the provisions set forth in Article 101 (3) TFEU are met. This refers to an agreement "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" (Article 101 (3) TFEU). The restrictions falling under Article 101 (3) TFEU further must not substantially eliminate competition regarding the concerned product and must be indispensable for the beneficial objectives (ibid.). The Commission assesses restrictions falling in the scope of Article 101 TFEU either as "restrictions by object" or "restrictions by effect". The difference is, that "restrictions by object" "by their very nature have the potential to restrict competition" which needs to be demonstrated by taking into account relevant factors and specifics of the agreements (European Commission 2014b, pp. 3). The Commission does not need to show "any actual or likely anticompetitive effects" in a "by object restriction" in contrast to "restrictions-by effect" where these assessments need to be made (ibid., p. 3). "By object restrictions" can still be exempted from Article 101 in case the parties can demonstrate the specified benefits which meet the provisions set forth in Article 101 (3).[14]

The newly adopted Commission guidelines on the assessment of technology transfer agreements include patent settlements as a unique and potentially problematic case group. The benefits of settlements, the problem of weak patents as well as the assessment of the reverse payment have a particular importance (European Commission Technology Transfer Guidelines, pp. 44). The Commission assesses whether restrictions which are part of the settlement fall under the Technology Transfer Block Exemption Regulation essentially constituting a safe harbor for categories of agreements based on the cartel exemption from Article 101 (3) TFEU. There are types of hardcore restrictions and other restrictions which can be per se problematic. Such restrictions (e.g. market sharing, price fixing) can also be part of settlement agreements. This only refers to situations where the settlement agreement extends the originators patent grant. Agreements between originators and generics which prevent entry of generics within the patent duration do not fall under these hardcore restrictions, since a valid patent grants exactly these monopoly rights. Such agreements are instead subject to review whether or not they fall under the cartel exemption. It cannot be said that specific types of settlements, we are discussing here, are generally falling under a safe harbor rule in the EU. The guidelines include the notion that, on the one hand, patent settlements can provide benefits like saving of litigation costs or resolution of uncertainty but, on the other hand, should not harm the public interest of an invalidation of wrongly granted intellectual property rights as a barrier for competition and innovation (European Commission Technology Transfer Guidelines, p. 44 at para. 235). Before discussing the Lundbeck case in detail, an overview should be given about other important patent settlement cases.

In Perindopril, a drug to control blood pressure, the Commission has taken action against originator Servier and several generic competitors on the basis of Article 101 and 102 TFEU. Servier's Perindopril was dominant in the market. The antitrust action was based on entry restrictions (including the ending of patent challenges) caused by agreements between 2005 and 2007 with reverse payments as well as through means of technology acquisition by Servier in 2004 which delayed generic entry. Total fines of €427.7 million were imposed. Patent protection, particularly through process patents, was assessed as being limited (the molecule patent in for the most parts had expired in 2003) and generics already had

[14] For a discussion about "by object" and "by effect restrictions" and its developments in the framework of Article 101 TFEU see Jones 2010, pp. 793.

prepared market entry. The Commission concluded that the objective of the abusive strategy imposed by Servier was to restrict and delay generic entry (European Commission 2014a).

In Fetanyl, a painkiller drug, fines have been imposed by the Commission on originator drug maker Johnson & Johnson (€ 10,798,000) and on Novartis (€ 5,493,000) for concluding an agreement which delayed the market entry of the generic version of the drug in 2005. The finding was based on an infringement of Article 101 TFEU. Part of the agreement was a payment from Johnson & Johnson to Novartis. Novartis, through its subsidiary Sandoz, was on the brink of entering the Dutch market in 2005 with its generic version of Fetanyl in patch depot form since the relevant patent of Johnson & Johnson had expired. However, Johnson & Johnson's Dutch subsidiary Janssen-Cilag and Sandoz concluded a "co-promotion agreement" in which Sandoz was paid to not enter the market. The payment from Janssen-Cilag to Sandoz exceeded Sandoz' expected profits in case of market entry (European Commission 2013a).

In Modafinil, a treatment for sleeping disorders, the patent settlement between the U.S. pharmaceutical firm Cephalon and the Israeli generic competitor Teva raised antitrust concerns both in the EU and the U.S.[15] The European Commission opened investigations with regard to Article 101 TFEU concerning the prevention of the entry of the generic version of the medicine into the market. In the settlement agreement Teva agreed not to sell its generic version until 6 October 2012 in the EEA which was three years before patent expiry under the inclusion of various side deals (European Commission 2011). The validity of Cephalon's patent was challenged by several generic competitors, including Teva, in the EEA (with success only in the UK. Teva and Cephalon completed a merger on 14 October 2011 which was cleared by the European Commission subject to the commitment to divest to a purchaser the generic version of Modafinil through transfer of assets and rights (including marketing authorizations and intellectual property), supply agreements and the provision of further assistance (Case M.6258 - Teva/ Cephalon).

4. The Lundbeck case

4.1 The Agreements

On 7th January 2010, the Commission opened formal proceedings in its first action in a pay-for-delay settlement case which concerns the "blockbuster" antidepressant drug "Citalopram" (European Commission 2013b). The Commission as a result of the antitrust assessment imposed fines on Lundbeck as well as the generics based on their infringement of Article 101 TFEU.[16] For the calculation of fines a particular importance is attributed to the value of the parties' respective sales relating to the antitrust violation, the gravity and duration of the violation as well as an additional amount based on the specifics of the cases. The Commission decision was appealed by Arrow Generics at the General Court. In early September 2016, the court dismissed the motion and affirmed the Commission's decision (General Court Case T-467/13).

[15] The antitrust investigation by the FTC in the U.S. concerned the conduct of Cephalon to prevent generic competition by paying its four generic competitors together more than $300 million through side-deals to abandon their patent challenges and refrain from entry into the market before April 2012 although generic entry was impending in late 2005. In the U.S. investigations, it was also an issue for specifying monetary remedies that the patent at issue was obtained by fraud (FTC Statement - FTC v. Cephalon, Inc).

[16] The imposed fines for the firms are: Lundbeck €93,766,000; Merck €21,411,000; Arrow €9,975,000; Alpharma €10,530,000; Ranbaxy €10,323,000 (Case at.39226 – Lundbeck, pp. 434-460).

H. Lundbeck A/S is a Danish originator pharmaceutical company consisting of a group of subsidiaries. The agreements which were examined by the European Commission were concluded with generic companies Merck Generics UK Ltd, Arrow Generics Ltd, Alpharma ApS and Ranbaxy Laboratories Ltd. All agreements can be regarded as relatively similar since in all cases a restriction of generic entry and value transfers from the originator to the generic were included. The Commission comes to the conclusion that the agreements violate Article 101 TFEU or respectively Article 53 of the EEA agreement which inter alia prohibits price fixing, market sharing or other forms of collusion. The core of the Commission's assessment is whether the parties to the agreement were potential competitors in the respective markets, whether a prevention of entry took place and whether the nature of the agreements were responsible for the entry delays. Lundbeck is the producer of the original version of the drug Citalopram which is an antidepressant drug. At the time of the problematic agreements, in early 2002, most relevant product and process patents as well as data protection of clinical studies needed for marketing approval for Citalopram had expired in various countries in Europe (Case at.39226 – Lundbeck, p. 94). So, the originator product was, at the time of the agreements with the generic firms, not entirely protected by intellectual property rights. Some ways to produce Citalopram were still protected by process patents which however gives generic producers an opportunity to use a different production method.

The generics concerned all had the prospect to enter the respective markets with generic versions of Citalopram. This is derived from the generic's existing supply agreements with suppliers of Citalopram API (Active pharmaceutical Ingredient[17]), existing marketing authorizations as well as generic Citalopram already being in stock. The agreements specified one or more of the following parts:
A) The generics delay their market entry (and partly do not provide other third parties with means to enter the market)
B) Generics submit or sell existing stock of their generic Citalopram to Lundbeck
C) Lundbeck would instead supply them with the original version of the drug possibly with a reduced price.
D) Lundbeck pays an amount of money to the generics
E) Future Citalopram generics based on potentially different production processes are similarly excluded/delayed from market entry.

Table 1

Lundbeck Agreements with Generics	Entry Delay	Agreement to Sell/Submit Generic Stock	Supply Agreement Lundbeck to the Generics	Reverse Payment	Exclusion of future processes
Merck GUK (with regard UK)	24 January 2002-1 November 2003	yes	yes	corresponding to lost profits from delayed market entry	
Merck GUK (with regard EEA)	22 October 2002-22 October 2003			corresponding to lost profits from delayed market entry	yes
Arrow (with regard Denmark)	3 June 2002-1 April 2003	yes		corresponding to lost profits from delayed market entry	yes

[17] This can be seen as an upstream product.

Arrow (with regard UK)	24 January 2002-20 October 2003	yes		corresponding to lost profits from delayed market entry	yes
Alpharma (with regard EEA/Norway)	22 Februar 2002-30 June 2003	yes		corresponding to lost profits from delayed market entry (a minor part specifically included prevented litigation costs by Lundbeck)	yes
Ranbaxy (with regard EEA)	16 June 2002-31 Dec 2003		yes	Exceeding value of manufactured generic stock	

Source: Own representation based on: Case at.39226 – Lundbeck, pp. 88-196; pp. 237 at para 693; pp. 252-410.

The Commission investigated that all agreements were the result of intensive consultations between the parties. The settlements were concluded at a stage were no litigation between the parties was taking place. However, there was the threat of infringement proceedings, partly already initiated by Lundbeck. The parties in their settlement agreement mostly expressed different views with regard to the question of patent infringement or patent validity. While Lundbeck made clear prior to the agreements that a marketing of generic Citalopram would cause patent violations, the generic firms mostly rejected these claims however acknowledging the possibility of a patent dispute. The goal of these preemptive settlements was, according to the parties, to inter alia save litigation costs (Case at.39226 – Lundbeck, pp. 412). However, the Commission identifies the entry restriction in form of collusive behavior as the main goal of the agreements.

4.2 The Commission's antitrust assessment

In the antitrust assessment of the settlement agreements the Commission used a *three-step test*.

- Firstly, it was determined whether the parties on the relevant markets were actual or potential competitors. Since Lundbeck Citalopram was under patent protection prior to the agreements generic competitors were not on the relevant markets. However, the question for the Commission was whether the generics would constitute a competitive constraint by being potential competitors.
-Secondly, the Commission assessed if generic entry was restricted or delayed beyond the scope of existing patents.
-Thirdly, the role of the reverse value transfer from the originator to the generic was assessed particularly its connection to the entry delay.
As a final step the Commission also assessed whether the agreements qualified for the Article 101 (3) TFEU exemption.

Since in Lundbeck no technology transfer between the parties occurred, the Commission guidelines on the assessment of technology transfer agreements were not applied explicitly. However, we can derive conclusions from the guidelines on how the Commission establishes its general patent settlement policy. In the following, the Commission's 3-step test shall be focused more closely.

4.2.1 Potential competition

Since the agreements in question covered cases in which the generics had not entered the markets, the Commission first addressed the problem whether the parties are potential competitors. The Lundbeck case represents an application of the concept of potential competition in light of existing intellectual property rights. There can be the argument that patent protection does not allow for potential competition since the market is not open for entry. However, this is only true for ironclad patents which absolutely block any entry (meaning patents which are valid with absolute certainty). In the Lundbeck case existing patents however were considered as being relatively weak so that entry is a possibility. The notion of potential competition and how to define it in the respective case is a non-trivial task for the Commission. For that assessment two factors are specifically important which go beyond the narrower question of patent strength: Were the parties able to enter the market at that time and was there intent to do so? In this context, the ability to enter is more important for the Commission than the actual intent (Case at.39226 – Lundbeck, p. 204).

Regarding the ability to enter the market the Commission focused on three categories: 1.) Technical means to enter the market; 2.) regulatory approval; 3.) existing Lundbeck patents which could constitute an effective barrier to entry for the generics. The effort to become a potential competitor is seen as reflecting the actual intent to enter the market especially in case sunk costs exist. The Commission regards the ability to become a potential competitor in the pharmaceutical industry as a 2-stage process of developing and preparing the means to enter the market. Potential competition already begins years before expiry of the product patent when the generics develop a production process which is feasible both commercially and with respect to the regulatory requirements. This is the phase were generic firms together with their suppliers of generic API, which can be seen as raw material for the final drug, need to figure out how they could bypass existing process patents by either inventing around that process while maintaining quality standards of the production process or seeking an invalidation of the patent. The second phase is marked by preparations for market entry by obtaining marketing approval, launching marketing strategies and by setting prices which can be subject to proceedings with national regulators and reimbursement authorities. Therefore, the Commission considers these partly very visible efforts by generics as an indication that they potentially compete with the originators. This is particularly true since the efforts and costs spent by the generics can be regarded as sunk costs (Case at.39226 – Lundbeck, p. 209). Interestingly also some statements by Lundbeck that a generic might infringe a process patent are interpreted as preemptive defense against market entry and therefore signs for the existence of potential competition between the parties. The criterion for the Commission to assess whether parties to the problematic agreements are potential competitors is if generics had a “business plan” and a “realistic prospect” to sell generic Citalopram. “Realistic prospect” means that the generics are likely to acquire generic Citalopram for sale as well as receiving a respective marketing authorization (ibid.). For the Commission to regard the parties as potential competitors it is not necessary to show that the 2-stage process of developing and preparing the ability to enter the market has been entirely completed. If e.g. the marketing approval for a specific generic product is missing, the generic still can be a potential competitor in case considerable efforts in that regard have been taken (ibid.).

The Commission addresses the question whether Lundbeck patents or other forms of intellectual property constitute an effective barrier to entry. Intellectual property such as patents and also existing protection on data for clinical trials needed for receiving marketing authorization are generally a market entry barrier and affect generics ability to compete (ibid., p. 213 at para. 628). The Lundbeck original compound patent on Citalopram had expired in 2002. This was prior to the conclusion of the agreements in most relevant markets. Although some process patents were still in place the Commission regards the markets as being open for generic entry in case marketing approval can be obtained. Very important is that in the EEA it is not necessary for generics to show that their product does not infringe any patents before obtaining

marketing authorization (Case at.39226 – Lundbeck, p. 211)[18]. The Commission's argument further relies on the possibility for generics to either invent around patented processes or to seek an invalidation of the process patents. An important question is however how likely it is for the generics to successfully invent around without risking infringement. The Commission cited numbers based on own assessments from Lundbeck that their crystallization process patent which was seen as important to prevent generic entry would face a likelihood of 60% of being invalidated by the United Kingdom patent court. Taking into account that the original compound patent had already expired as well as patents on two original production processes, generic entry was regarded as much more likely than just the mere possibility (ibid., p. 212, at 627). Generally, the Commission considers patent litigation, patent challenges or infringement allegations as part of (potential) competition in the pharmaceutical sector (ibid., pp. 209 at para. 212). Therefore, attempts to slow down or eliminate that process can also be seen as impediment to actual or potential competition. In the case at hand the Commission clearly made an assessment based on evidence from the parties' own assessment of the strength of the patents. In seems also clear that such an assessment is necessary to draw the line whether patents or other intellectual property constitute a barrier to generic entry. On the one hand, the validity of patents seems to be a well-established assumption (ibid., p. 213 at para. 628) and, on the other hand, the notion of certainty of infringement is rejected (ibid., p. 214 at para. 629). Thus, in the case at hand it needs to be assessed whether the patent is sufficiently weak for the existence of potential competition or whether it is sufficiently strong for this being not the case. To exemplify this way of thinking two extreme cases can be used: Even if the patent protection is extremely strong, there always exists the possibility for generics to enter at risk. This does not mean that any generic facing this extremely strong patent is a potential competitor. On the other hand, if there exists just the possibility that a product or process might be infringing this does not mean that the firms cannot be potential competitors just because they are facing patents. The Commission believes that patent holders decide based on business prospects whether they start infringement proceedings or not. So even if a product or process might be infringing the patent holder could decide not to start proceedings since it is not worthwhile in that situation for the firm. So, the mere possibility of infringement cannot per se mean that the parties do not compete (Case at.39226 – Lundbeck, p. 215, at para. 631). Thus, part of the concept of potential competition used by the Commission is that there exist "realistic grounds" for market entry also meaning an invalidation of a patent or non-infringement of a product or process patent in the case at hand (ibid., p. 213 at para. 628, European Commission Guidelines on the applicability of article 101 of the treaty on the functioning of the European Union to horizontal co-operation agreements, p. 5). Lundbeck itself states that an infringement of process patents which was the only intellectual property barrier for generic entry is harder to prove than an infringement of product patents (Case at.39226 – Lundbeck., p. 214, at para. 629).

Through either launching the generic product at risk, trying to invalidate Lundbeck's existing process patents or inventing around the existing process patents the generics could have entered the market (ibid., p. 217 at para. 635). Also, there existed methods to produce Citalopram without infringing Lundbeck's process patents particularly without using the crystallization process. So, the prospect for generics to enter the market was realistic at the time which makes them competitors to Lundbeck.

4.2.2 Entry restrictions

The next step in the Commission's assessment of the Lundbeck agreements is the competitive assessment of the restriction of competition by the agreements. From that assessment, some general remarks from the Commission regarding this particular group of agreements can be analyzed.

[18] This is referred to as "Patent Linkage" (European Commission 2009, p. 315).

The criterion the Commission is using in Lundbeck is to check whether the agreements in question fall outside of the (probabilistic) scope of the patent and therefore infringe Article 101 TFEU[19]. The Commission's argument in Lundbeck at this point is based on two elements:

-An assessment of what a patent can normally exclude and comparing that to the exclusion the parties have reached with their agreement.
-An assessment of the parties' beliefs of the patent strength and comparing that to the outcome of the settlement.

As shown before, patents are not always seen as purely valid or invalid. The question is whether the patents constitute an effective barrier to entry. The effectiveness of the barrier to entry of patents is determined by the strength of the individual patent and the patents collectively. As we have seen, this mostly depends on the likelihood that originators prevail in an infringement suit or maintain the validity of patents. If this likelihood is high enough this would probably deter generics from entering at risk or entering at all thus making early competition unlikely. If this likelihood is relatively small, then early competition can be expected because entry cannot be effectively deterred. A patent holder has the possibility to sue a generic firm in a court where judges decide upon infringement and patent validity. Lundbeck's blocking power vis-a-vis the generics is based on the prospect that (1) from a business perspective it is feasible for Lundbeck to sue, (2) a court finds that a particular process to manufacture Citalopram used by a generic is infringing, (3) the patent is not invalidated and (4) the generics do not find a different process to manufacture the drug which is not infringing. A settlement agreement which grants Lundbeck the certainty that generics stay out of the market for a defined period of time is clearly more than what can be expected by a process patent (Case at.39226 – Lundbeck, p. 220 at para. 642). A specific notion which the Commission is attacking is that parties agree on exclusions which do not take into account that the patent dispute is based on alleged infringements not on actual infringement as decided by a court (ibid., pp.145 at para. 394). To support that argument, the Commission finds evidence that generic competitors entered the market previously although Lundbeck's crystallization process patents were still in place (Case at.39226 – Lundbeck, pp.232 at para. 677). Thus, restrictions in the agreements go beyond the exclusionary scope of the patents (ibid, p. 229 at para. 662).

For the Commission, it is also clear that the parties might have different opinions about the likelihood of patent validity or infringement. As a result, agreements between the parties in a patent dispute must not restrict generic entry more than reflected by the strength of the patents as assessed by the parties (ibid., p. 219 at para. 638). This is the second element of the argument which is used by the Commission to define a restriction of competition in the light of Article 101 TFEU. The parties' own assessment of the blocking potential of patents is analyzed. This is done by taking into account all available evidence like past court decisions, relevant data or statements by the parties themselves. Thus, the Commission tries to assess from an objective point of view what the parties might have thought about the patent strength when they negotiated the agreement. In case the entry restriction in the patent settlement is not consistent with that perceived (objectified) patent strength of the parties this is a restriction of competition in the light of Article 101 TFEU. By looking at what a patent can normally exclude and comparing it with the actual entry restriction through the agreement the Commission does not necessarily need proof of reverse payments.[20]

[19] The notion of "probabilistic patents" refers to patents which might be valid with a certain probability (Shapiro 2003, Leffler/Leffler 2003, Lemley/Shapiro 2005, Farrell/Shapiro 2008, Encaoua/Lefouili 2009). The notion of "probabilistic patent scope" refers to the restriction of entry which a probabilistic patent provides (e.g. Elhauge/Krüger 2012).

[20] This is important since there might be cases other than Lundbeck where the reverse payment/value transfer takes different forms and might be hard to identify (European Commission 2015a, p. 3 at para. 12).

Rather it is a very general argument. This argument, however, is stronger when combined with the notion of a relatively weak patent and the importance of the reverse payment.

4.2.3 Reverse payments

The third step is the Commission's assessment of the reverse value transfer paid by Lundbeck and linking it to the restriction of competition. This payment or value transfer from the originator to the generic is a clear indicator for the Commission that the restrictions in a patent settlement are a form of collusion and do not represent the patent strength. In that sense, the assessment of this payment is deeply related to the second assessment step to ask whether there are restrictions of competition not reflected by the perceived patent strength of the parties. If a reverse payment is included in a settlement it is exactly this payment in combination with the negotiated entry restriction which should reflect the respective assessment of the patent strength. So, by inclusion of the payment there is no clear connection anymore between perceived patent strength and entry restriction. Since both firms have an incentive to collude, the restriction with inclusion of the reverse payment is likely to be larger than purely based on the patent strength. A patent holder who thinks that the patent is rather weak and sees high value in preventing generic entry is also willing to pay more to the generic to stay out of the market (Case at.39226 – Lundbeck, p. 220 at paras. 640, 641). Therefore, the willingness to pay to prevent generic entry is firstly a function of the strength of the patents and secondly a function of the value of the patent for an originator. It is very important that for the Commission not all payments from originators to generics need to be anticompetitive because they delay entry. Specifically, such a reverse payment could be justified where used not to delay entry but to compensate for delayed entry caused by a too optimistic belief in the patents validity by the parties (ibid., p. 219 at para. 639). Thus, as long as the settlement and its terms do reflect the parties' genuine beliefs about patent validity this is an indicator for the agreement being within the patents exclusionary scope. In Lundbeck, on the contrary, the Commission has clear evidence that the amounts of the reverse payments in the agreements are linked to lost profits from generic entry delay (see *Table 1*, Case at.39226 – Lundbeck, p. 229 at para. 662).

The existence and size of the reverse payment are used by the Commission to make the case that the parties themselves assess the patent as relatively weak and at the same time that the originator is inducing the generic to stay out of the market. Thus, the reverse payment is both an indicator of a weak patent and an indicator of collusion whereas the former is a precondition for the latter being anticompetitive. The reverse payment being the cause for the generic to stay out of the market is also supported by Lundbeck not having committed to refrain from suing generics for infringement after the end of the agreements. So, the main purpose of the agreements is not seen as the settlement of patent litigation (since this could theoretically continue after the agreement) or clarification of patent validity but as a mutually beneficial entry delay (Case at.39226 – Lundbeck, p. 229 at para. 662). The argument brought forward by Lundbeck that the agreements were concluded at a time when patent litigation (and thus clarification of the issue) was already pending was rejected by the Commission. In fact, Lundbeck was in patent litigation with the UK generic firm Lagap Pharmaceuticals Ltd. which started in 2002 after the conclusion of the settlement agreements. Lundbeck had sued Lagap for infringing their process patents on Citalopram but both firms settled before the court could decide on the case in 2003 (ibid., p. 235 at para. 683). Lagap received a royalty-free license to use Lundbeck's process patent for generic Citalopram while Lagap stopped the invalidity challenge against Lundbeck's important crystallization patent (ibid., p. 84 at 207). The previously concluded settlement agreements were not tied or dependent on the resolution of the Lagap case and the argument both would have been related and based on the clarification of the validity issue is not convincing to the Commission (ibid., p. 237 at para 688).
By using these arguments, the Commission can build a strong case which does not solely rely on their interpretation of the reverse payment but also on the general idea of the restriction being stronger than in reach through the probabilistic scope of the patent which is again supported by existence of the reverse

payments. Moreover, the Commission uses data from parties and competitors as well as other evidence (e.g. court rulings) to support their argument that the limited blocking potential of existing patents was artificially extended. In one case, there is evidence that existing generic marketing authorizations could not be transferred or sold to third parties as part of the agreement (Case at.39226 – Lundbeck, pp. 266 at para. 763). This clearly shows that Lundbeck wanted to exclude any competition and was not focused on clarifying patent disputes with specific parties. This is important since deriving anti-competitiveness only based on reverse payments can be problematic because these payments might also be justified or be based on incorrect beliefs of the parties. A patent might in fact be very strong but in case the parties use a reverse payment essentially because of wrong beliefs about the patent strength the Commission might be prone to falsely prohibiting settlements (type 1 errors).

4.2.4 Efficiency effects

The Commission was able to identify that Lundbeck's actions were part of an overall strategy to prevent generic entry not based on the patents actual strength. In fact, the restrictions go beyond the scope of the patents. These considerations lead to an assessment scheme in which the Commission takes into account if the parties (potentially) compete with each other, if there is a generic entry restriction and if there is a value transfer from the originator inducing the generic to not compete anymore (Case at.39226 – Lundbeck, p. 228 at para. 661). In a final step the Commission takes into account possible efficiency advantages through these agreements. It is important to note that this is different to the previous assessment whether there might be justifications for the reverse payment paid by Lundbeck to the generics. In the former analysis, the Commission tried to clarify whether the reverse payment really was an instrument to delay market entry (which would not necessarily be the case if other justifications for that payment exist). However, in this analysis the question is, if consumers benefit from the agreements. According to Article 101(3) TFEU the prohibition of horizontal agreements can be exempted in case efficiency advantages can be gained through such agreements which benefit consumers. Any restrictions of competition through these agreements need to be indispensable for these efficiencies to occur and may not eliminate competition (European Commission Guidelines on the application of Article 81(3) of the Treaty[21], p. 97). The arguments which are brought forward by parties in terms of potential efficiency gains relate to:

1) Saved litigation costs
2) Better distribution of Citalopram
3) Earlier market entry than without the agreement

The Commission argues that none of these claimed efficiencies are relevant regarding Article 101(3) TFEU. It is not clear whether the parties by engaging in these settlements saved litigation costs since the settlements did not resolve the question of patent validity or infringement. This means that litigation was suspended during the agreements but not necessarily afterwards. Also, the parties failed to prove that such savings in litigations costs could have benefitted consumers. To qualify for an Article 101(3) exemption the savings would need to decrease prices for consumers or benefit them in other ways. The argument that in some cases the distribution of Citalopram could have been improved is not convincing for the Commission either. Firstly, it is not sufficient that in some areas e.g. through supply agreements between Lundbeck and generics there might be an improved distribution while in other areas consumers are worse off because of the agreements. Secondly such claimed benefits could have been created also without the restrictions included in the agreements. And thirdly the benefits could not clearly be substantiated. The third argument, which is also not convincing for the Commission, refers to alleged earlier market entry than in the case without the agreements. It is clear for the Commission that

[21] Article 81(3) TEC is today called Article 101(3) TFEU.

Lundbeck's strategy aimed at preventing generic market entry. After the agreements had run out there was no commitment that the generics could safely enter the market. Also, there is no evidence that an earlier market entry of generics would need to go along with entry restrictions set forth in the agreements (Case at.39226 – Lundbeck, pp. 410-414).

4.3 Review of the General Court

With decision of September 8, 2016 the Court of Justice of the European Union - General Court - issued a ruling in which it dismissed the motion of Arrow Generics to partly annul the Lundbeck ruling and reduce the fine. The court particularly assessed whether the Commission was right to regard the parties as potential competitors in the light of patent rights, whether the Commission was right to conduct a "restriction by object" assessment and whether the Commission was right to conclude generic entry restrictions on the basis of finding reverse payments. In its ruling the General Court affirmed the Commission's view that Lundbeck and the generics were potential competitors at the time of the agreements and that the protection of potential competition is part of Article 101 TFEU. It is stated that the mere theoretical market entry (like the possibility to eventually successfully challenge the patent and enter the market) does not suffice for finding potential competition (General Court Case T-467/13 at para. 68). The Court confirmed the Commission's approach for the assessment of potential competition to take into account also the parties own perception of the likelihood of generic entry. Arrow had argued that the finding of the existence of potential competition needed to be objectified to also exclude the possibility of a party bluffing about its prospective entry (ibid. at paras. 62-92). More generally, the Court points at the requirement to show a "real concrete possibility of the undertaking concerned entering the market within a reasonable period"[22] (ibid. at para 107) which the Commission was able to show in Lundbeck. This notion of potential competition is, according to the court, compatible with a presumption of the validity of patents since there is also no presumption that any product entering a specific market certainly infringes these patents. On the contrary, patents do not grant protection against challenging of patents (ibid. at paras. 103-112). Accordingly, the agreements in Lundbeck are assessed on the basis that they impede generic market entry and in particular patent challenges constituting a form of (potential) competition. Regarding the "by object restriction" assessment the Court notes that also a restriction of potential competition, like in Lundbeck, can constitute a "by object restriction" (ibid. at para. 249). It is established that all factors combined, regarding objective, content and context of the agreements, point to a "restriction by object" (ibid. at para. 273). The Court broadly follows the Commission's argument by regarding the value transfer as instrumental to turn the uncertainty of the patent dispute into certainty of market exclusion constituting a "restriction by object". The counterfactual, to actually show that the generics would have entered in case of ongoing litigation, is not required (General Court Case T-467/13 at paras. 250, 251). Regarding the reverse payment, the Court points to the necessity to assess also the context of this payment. The Commission analyzed the payment in the context of competition between the parties and the imposed restrictions in relation to the payments. This assessment is affirmed by the Court (ibid. at para. 300).

4.4 Economic assessment of the Lundbeck case

Lundbeck is an exemplary application of an analysis of price effects in patent settlements. The Commission based the argument for finding an antitrust violation on the illegitimate entry delay of generics into the market. Based on what we know until now from economic theory, the following criteria are relevant for patent settlement assessment:

[22] E.g. by examining preliminary steps necessary for a market entry (General Court Case T-467/13, at para. 112).

1. Assessment of potential competition and particularly the patent blocking power. This includes also quantifying the weakness of the patent. Assessment of how the institutional framework of the pharmaceutical sector affects potential competition. The analysis includes developing counterfactual scenarios (i.e. prospective generic entry without the settlement).
2. Quantifying the reverse payment (and eventually using it for deriving the patent strength).
3. Assessing the settlement terms as a result of a complex bargaining process taking into account all relevant factors including litigation and settlement costs, asymmetric information, different beliefs and the institutional framework). Re-examination of the role of the reverse payment for identifying pro- or anticompetitive settlements.
4. Taking into account how the settlement terms influence innovation incentives and challenging incentive effects for identifying pro- or anticompetitive settlements.

How does the Commission's assessment in Lundbeck relate to what we know from economics? Criteria that are included in the analysis carried out by the Commission particularly refer to the assessment of potential competition/entry restrictions and the reverse payment (criteria 1 und 2 above). The weak patent argument can be seen as an extension of the analysis if and how parties compete with each other. This is usually done by delineating markets and analyzing market entry barriers. In case patents are weak, it is important to find ways to quantify this weakness for the analysis of market entry barriers and potential competition. The Commission shows evidence that the own estimate from Lundbeck of the likelihood of an invalidation of their important crystallization process patent would be at 60% in the United Kingdom (Case at.39226 – Lundbeck, p. 212, at para. 627). Also, there is evidence that the generics prior to the agreements mostly rejected claims by Lundbeck that products or processes would be infringing, only recognizing the mere chance of patent disputes. From the evidence collected the Commission is rather certain that the patent protection is nowhere near ironclad and that the chance of market entry before patent expiry would be rather high. The agreements involved substantial reverse payments, exceeding litigation costs, as well as fixing of generic entry dates and the Commission can directly connect the reverse payments to lost generic profits from the entry delay.

How did the Commission address the fact that the Lundbeck case refers to settlement agreements in different jurisdictions with different regulatory frameworks? This is, as we have previously discussed, relevant for the bargaining process, and therefore the outcome of the settlement, and the antitrust assessment. Particularly the weakness of the patent might vary in different countries. In analyzing potential competition regarding prospective generic market entry and in analyzing counterfactual situations regarding entry restrictions taking into account country or region specific situations, the Commission conducted a thorough analysis. The final result of this analysis can be supported.

We have seen that economic reasoning suggests that settlement agreements with substantial reverse payments can, under specific circumstances, be welfare enhancing. To what extent are such effects relevant in Lundbeck? In patent settlements efficiency effects for creating consumer benefits might play a role in two scenarios: First, efficiency effects like the saving of administrative costs or resolution of uncertainty might be such as to outweigh negative price effects from a generic entry delay. Second, saved litigation costs influence the bargaining situation in patent settlements. This means they need to be taken into account in case the reverse payment is seen as a proxy for the entry delay based on the weak patent notion. Litigation costs or their prevention are mentioned by the Commission in their analysis of efficiency claims by the parties.[23] Although Lundbeck as well as generics claim significant savings of litigation costs and time through the settlement agreements, this is not specified exactly in most cases (Case at.39226 –

[23] Regarding the agreement between Lundbeck with Alpharma there is evidence that Lundbeck saved 1 Mio USD by preventing litigation and also saved time (Case at.39226 – Lundbeck, p. 371 at para. 1068).

Lundbeck, pp. 412)[24]. To really make the case of efficiency advantages through saved litigation costs the Commission points out that this requires a clear specification and connection between the saved costs and consumer benefits (ibid., pp. 410-414) which can be supported from an economic perspective. For finding justifications for reverse payments economic theory suggests that they lead to earlier market entry. The Commission in Lundbeck does not find evidence for earlier market entry or better drug distribution which might outweigh the negative price effects. Thus, the agreements made consumers worse off compared to a situation in which the generics would have attempted to enter the market earlier and patents would have been litigated. Taking into account the specifics of the Lundbeck case a deeper economic analysis of the settlement terms and bargaining positions (criterion 3 above) would very likely not have changed the final antitrust assessment.

We can derive from economic theory that factors exist, besides price effects, which influence consumer welfare and can create tradeoffs in the assessment of patent settlements (challenging incentive effects, innovation incentives, see criterion 4 above). This can mean to accept later generic market entries and reverse payments or to find anticompetitive effects even without reverse payments. Innovation incentive effects as well as challenging incentive effects are not included in the Lundbeck assessment. Economic rationales suggest that investigations in patent settlements should not ignore both effects. Based on the fact that we do not know how to fully integrate price-, innovation- and challenging incentive effects, the Commission's focus on the well understood price effects can be supported. There is also no evidence that taking into account innovation incentives and challenging incentives effects could outweigh the negative price effects in Lundbeck. From an economic perspective, it is even possible that these effects even lead to stronger concerns regarding consumer welfare harm of the agreements. Overall, taking into account the clear relevance of anticompetitive price effects in Lundbeck, the Commission's decision, as affirmed by the General Court, can be supported from an economic perspective. Although the Commission does not take into account every relevant factor, it covers the most relevant aspects for the specific Lundbeck case and convincingly derives caused consumer harm from the agreements. To what extent the test can be an example for different cases, case groups or the more general problem of assessing patent settlements remains questionable, keeping in mind how specific the case is. In the literature, mainly in the legal discussion about the case, authors seem to recognize the factors which have led to the Commission's decision. However, questions are raised regarding the applicability of the Lundbeck test to other forms of agreements and some authors point at a lack of consistency in the approach and criticize particularly the "by object" assessment standard (Killick et al. 2014, pp. 5, Gallasch, 2015, Zafar 2014).

5. Patent settlements in the EU: Analysis of principles and problem areas

As we have seen, the Commission is correct in including direct evidence of weak patents in their Lundbeck analysis which essentially consists of the 3-step test (potential competition, entry restrictions and reverse payments) and the analysis of efficiency effects. This leads them to find negative price effects from generic entry delay. The question now needs to be raised, what are criteria for finding anticompetitive effects based on the weak patent argument in patent settlements more generally and what is already specified by the Commission? What problems can be identified in that regard? This relates specifically to the problem of potential competition, prevented patent challenges and the feasibility to see reverse payments as a proxy for anticompetitive harm.

5.1 Problems in defining potential competition

The very relevant question regarding potential competition in agreements involving intellectual property is

[24] Expect for the Alpharma agreement where specific numbers are presented (see fn. 23).

addressed in the Commission's Technology Transfer Guidelines. The reason why correctly assessing potential competition in patent settlements is important is due to the necessity to specify a counterfactual to the settlement. This means specifying what would have happened in a scenario without the settlement: More, less or equal competition? Entry restrictions are effective if they relate to potentially competing firms. It is noted that an assessment of potential competition includes and assessment of potential blocking positions though intellectual property between parties of an agreement (European Commission Technology Transfer Guidelines, p. 10 at para. 32). However, also the General Court argued in the aftermath of the Lundbeck decision that this does not preclude an investigation in the exact merits of such a blocking position. Even if there is a presumption of patent validity there is not a presumption of the existence of a blocking position which would mean excluding the possibility of a successful patent challenge, inventing around or non- infringement. It is the policy in the EU in the assessment of patent settlements that the parties of an agreement therefore need to proof that a blocking position does exist (General Court Case T-467/13 at paras. 159-163). Although the guidelines do not explicitly specify how forms of parallel intellectual property rights should be taken into account if a patent settlement is assessed, this also is relevant for the assessment of blocking positions or market entry barriers. This could be an issue in cases were multiple product or process patents exist or different forms of intellectual property. These different forms of intellectual property can include regulatory protection granted by drug approval agencies such as marketing exclusivity which constitutes an exclusivity right independent of a patent or data protection for clinical trials (Fackelmann 2009, p. 554). There might be cases where only the combination of different forms of intellectual property (including product and process patents and regulatory protection) can constitute a strong barrier to generic entry or this combination entails weaknesses offering loopholes for generic competition. In case a process for the production of a drug is protected by a patent but not the specific substance, this could give the generic the chance to enter with an altered production process (like in Lundbeck). In case an originator could prove the existence of other barriers against generic entry (besides the disputed patent), antitrust authorities could not easily argue that generic entry would have been prevented through the settlement. This is particularly true since there might exist cases where other forms of protection are even more important than patents (Fackelmann 2009, p. 555). Although the different forms of intellectual property have a high relevance in the pharmaceutical sector their exact functioning is clearly different in different jurisdictions. In Europe, even though the Technology Transfer Guidelines not explicitly take parallel intellectual property into account, this phenomenon might be captured in the assessment whether settling parties are actual or potential competitors as well as their degree of market power which is part of the Commission's assessment of patent settlements (European Commission Technology Transfer Guidelines, pp. 44 at paras. 239, 241). Again, it should be noted that such an assessment is important for finding actual entry delay effects in patent settlements based on prospective generic entry (which is also true for analyzing technical means of generics to enter the market).

5.2 Prevented patent challenges under weak patents

Negative price effects in patent settlements are not only a result from later entry of generics which are parties to the agreements, but also that of other third party generics which could not enter earlier (in expectation) because the patents validity was not tested in court. So, we have to distinguish two cases: The actual generic entry delay and the potential generic entry delay resulting from a patent settlement. The Commission, as in Lundbeck, focuses on the actual generic entry delay, underlining it with the likelihood of prospective market entry and reverse payments. However, it can also be argued that patent settlement agreements, even if the parties not directly or potentially compete on the market, have an influence on consumer welfare. Every settlement takes away the prospect that the patent might be invalidated with effects on other potential competitors and consumers. This is essentially a result of the weak patent argument. Analyzing the technical means of generics to enter the market or analyzing also other market entry barriers (including other form of intellectual property) is relevant for the question if

actual entry is possible and therefore can be delayed but is not required for the argument that potential entry effects are caused through the prevention of the patent challenge. Lundbeck is a case where direct entry delays are very clear. The Commission is right to regard also patent challenges as a form of competition (Case at.39226 – Lundbeck, p. 212). Consequentially, no-challenge clauses in patent settlements are regarded as inherently restricting generic entry (European Commission 2015a, p. 3 at para. 9). Although the mere prevention of a patent challenge can, even in the absence of prospective entry of a settlement party, be problematic based on the weak patent argument, there is evidence that the Commission does not strictly follow this logic. In Lundbeck prospective generic entry was an essential part of the argument for assessing the parties as potential competitors (not the mere existence of patent challenging). This is also in line with the more general approach of the European Commission.

The Technology Transfer Guidelines specify the tradeoff between benefits through the settlements themselves and the costs of unchallenged weak patents. The main problem that patent settlements can prevent the chance that weak, unjustified patents can be challenged in courts is therefore implicitly included in the guidelines (European Commission Technology Transfer Guidelines, p. 44 at para. 235). The assessment of no-challenge clauses in patent settlements follows this logic. First of all, the adapted Technology Transfer Block Exemption Regulation states that no-challenge clauses in licensing agreements whether directly or indirectly imposed fall outside of the block exemption having regard to Article 101 (3) TFEU (Commission Regulation (EU) No 316/2014, Article 5). The accompanying guidelines however specify that in the context of settlement agreements such no-challenge clauses are inherent to the agreements and generally fall outside the scope of Article 101 TFEU. At the same time, no-challenge clauses can be problematic in specific cases, namely where there is a reverse payment or the patents concerned were granted on the basis of false information (which would be equivalent to an extremely weak patent)[25]. Thus, a reverse value transfer is seen as a proxy for the anticompetitive potential of a settlement not only in terms of inducing the generic to stay out of the market but also in terms of preventing a patent challenge (European Commission Technology Transfer Guidelines, p. 44 at para. 239). A different interesting point in the guidelines refers to agreements between originators and generics in cases where the patent is required for the licensee's production. Problematic for the Commission are cases where originators deter generics not to challenge patents by threatening to terminate the licensing agreement which is necessary for their production. This can be true especially for situations in which the generic made considerable investments which increase the potential leverage of the originator to deter patent challenges by imposing such a threat (European Commission Technology Transfer Guidelines, p. 28, pp. 44 at paras. 136, 243).[26] It becomes evident that for the Commission it is not part of the

[25] Settlements involving a patent which was granted on the basis of false information point to the patent applicants fault in misleading the patent office and afterwards engaging in a settlement to prevent an invalidity claim (European Commission Technology Transfer Guidelines, pp. 45 at para. 243). The Commission herein refers to an extreme situation which involves fraudulent behavior of the applicant which the patent office could not detect or which ex-post information revealed and leads to a (certainly) invalid patent because the patent office made a mistake in granting or defining the patent. Such a scenario could be compared with an agreement involving an extremely weak patent. The Commission particularly sees an antitrust problem in case a courts ability to revoke the patents validity is impeded by a no-challenge clause. It is not so clear however if courts necessarily make better decisions than patent offices.

[26] However, these situations may be very hard to detect for competition authorities since they probably only can take antitrust action, if they can do it at all, if a licensing contract was actually terminated because of a patent challenge and not in advance. For a generic the decision not to challenge is however based only on the ex-ante threat. Therefore, if a cancellation of licensing contracts due to a patent challenge cannot be observed, this would not mean such a deterrence system of originators would not exist. In such a scenario patent challenges, might be prevented not by a value transfer but by threatening to negatively impact production. In cases where generics have various business relations with originators this might give the patent holder leeway to deter generic patent challenges and therefore keep weak patents in the

exclusionary scope of the patent to exclude any patent challenges European Commission Technology Transfer Guidelines, p. 45 at para. 243).

Cases like Lundbeck or Lundbeck/Neolab point to a more conservative interpretation of the guidelines by the Commission since not the mere prevention of a patent challenges is seen as problematic. In Lundbeck/Neolab a reverse value transfer was assessed as unproblematic while having a direct connection to a prevention of a patent challenge and potential patent invalidation.[27] Therefore, no-challenge clauses in patent settlements are not generally problematic, but they are also not generally exempted from antitrust scrutiny particularly in case reverse payments are involved. From an economic perspective, it is correct to not generally exempt no-challenge clauses in patent settlements from antitrust scrutiny. Reverse payments, the fact that both parties directly or potentially compete or further evidence of weak patents are good indicators for harm no-challenge clauses can create. However, since these clauses always have third party effects, there is good reason to broadly apply antitrust rules in that regard.

5.3 Reverse payments as a proxy for anticompetitive harm

Are reverse payments generally a good indicator for anticompetitive harm? The economic literature on patent settlements shows that bargaining between parties can be influenced by various factors and can change settlement outcomes. The analysis of reverse payments therefore needs to take these factors into account when assessing if reverse payments lead to welfare enhancing or welfare decreasing settlements. It is evident that this task can be extremely difficult. We know also that settlements with zero reverse payments can be anticompetitive.

For example, even in case the competition authority would provide evidence about asymmetric beliefs about the patent strength, which influence the settlement range, it would be necessary in such an analysis to have an objective indication for patent strength compared to the parties' beliefs. To accordingly estimate the patent strength can be very difficult. If investigations, similar as in the Lundbeck case, reveal different signals like litigation outcomes at different points in time and in different regions as well as documented internal communications, one might be able to draw from this evidence estimates about an objective patent strength. However, where this is not possible the sole indicator can be the parties' own assessment of patent strength which makes it difficult or impossible to assess whether one firm is overly optimistic or not or even tries to deceive the authorities. But, if competition authorities follow a strict consumer welfare standard it is necessary to take these factors into account and make appropriate assessments. This might lead to accepting also settlements with reverse payments above litigation costs in special circumstances following the logic of Article 101 (3) TFEU referring to an indispensability of a particular restriction for an increase in consumer welfare. Likewise, it might lead to prohibiting settlements without reverse payments. Reverse payments can also directly relate to efficiency effects. The guidelines do specify potential benefits of settlement agreements (e.g. saving of litigation costs or resolution of uncertainty) but not how exactly they should be taken into account or how they relate to justifying reverse payments (EC 2014, Technology Transfer Guidelines, pp. 45 at para. 235). The Lundbeck/Neolab

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market.

[27] Lundbeck settled with Neolab Ltd. to prevent ongoing litigation about the validity of the crystallisation patent regarding the UK market. Lundbeck's own assessment of the possibility to lose the litigation (by non-infringement or invalidation of the patent) was at 90%. Neolab was compensated by Lundbeck for an earlier acceptance of voluntary injunctions which had prevented its market entry. At the same time, Neolab refrained from seeking damages against Lundbeck in litigation while Lundbeck refrained from asserting patent claims against Neolab for past and future sales for a specified time in the UK. However, Lundbeck did enforce the patent in other markets. The reverse payment was assessed as not having the objective to delay market entry but to settle the patent dispute. The crystallization patents validity was, because of this and other settlements, not resolved by the UK court (Case at.39226 – Lundbeck, p. 70 at para. 164).

settlement involved a reverse payment which was seen as an unproblematic compensation payment enabling the resolution of a patent dispute while not preventing market entry. This case also shows that settlements involving commitments by the parties to facilitate market entry can be assessed as being procompetitive (see fn. 27).[28] It is acknowledged that despite reverse payments are a signal for anticompetitive harm, there might be situations where they are justified in particular where the generic is genuinely compensated by the originator e.g. for an unjustified blocking of market entry in case of a high likelihood of patent invalidity or non-infringement in the past (Case at.39226 – Lundbeck, pp. 219 at paras. 639, 640). It should be noted that from an economic perspective these justifications for a payment are particularly important if one tries to derive from the payment the weakness of the patents. Whether consumer benefits through saved administrative costs in reverse payment settlements might be so large as to countervail later generic market entry or how such an assessment should be carried out, remains questionable.

Besides the difficulties in assessing the anticompetitive potential of reverse payments, it can also be very difficult to merely quantify the (problematic) reverse payments. It is very important to note that "(…) virtually every patent license can be viewed as the settlement of a patent dispute (…)" (Shapiro 2003, p. 395). The Commission is not referring to reverse payments but to reverse "value transfers" in its guidelines which might indicate a higher complexity in their assessment (European Commission Technology Transfer Guidelines, pp. 44 at para. 238). Although the reverse value transfer is seen as a strong signal for consumer harm and plays an important role in the guidelines, it is not specified how exactly the scope of the value transfer can be assessed. It is not clear above which threshold a value transfer is "*significant*" or not. The main problem is that value transfers can be diverse, as the Commission correctly notes (European Commission 2009, p. 269). The assessment of a value transfer on a case-by-case basis is a very complex task especially when keeping in mind that value transfers do not consist solely of monetary transfers. Agreements might include cross-licensing, distribution-side-deals or originator non-assert clauses[29]. Cases in which the generic pays an amount for the license of an originator can also turn out to be reverse payments (in case the license is much more valuable than the reverse payment). A proof would, however, require a potentially difficult assessment of patent or technology values (European Commission 2015a, p.3 at para. 12, Bulow 2004, pp. 169). A different possibility for a (hidden) reverse value transfer are so called no-authorized generics obligations in which a brand manufacturer commits not to sell authorized generics.[30] Taking these factors into consideration we see that reverse payments are a strong signal for anticompetitive harm but only if an analysis is accompanied by scrutiny of various factors. This is necessary since patent settlement analysis is complex and holding them pro- or anticompetitive does not allow for just considering one part of the problem. We will discuss later whether we should go in this direction or rather follow a more pragmatic approach. First, we are looking at what we can learn from U.S. patent settlement policies and differences in institutional frameworks.

6. Learnings from the U.S., institutional frameworks, and policy perspectives

The adapted EU framework for the assessment of patent settlements indicates that restrictive terms included in settlement agreements are likely violating EU competition rules if they extent the scope of the

[28] On the other hand, it is also clear that even earlier market entry of one generic does not prevent others from being blocked if a successful patent challenge is prevented.
[29] The patent owner declares not to assert its patent against a generic.
[30] Authorized generics are sold directly by the brand manufacturer or an authorized generic and chemically identical to the brand product. They carry the same marketing approval than the original drug (FTC Press Release "No- Authorized-Generics".

patent by the use of hardcore restrictions (e.g. price fixing) or include certain elements (e.g. forms of no-challenge clauses and value transfers) not being in line with the presumption that these settlements can be beneficial for consumers. In the U.S., patent settlements have been reviewed extensively by courts, antitrust authorities as well as economic and legal scholars. This section shall examine what is different in the U.S. compared to Europe and what we might learn from the American approach. First, the patent settlement discussion in the U.S. shall be highlighted.

6.1 The U.S. patent settlement debate

U.S. Antitrust authorities and courts have extensively dealt with the patent settlement problem.[31] On June 17 2013 the U.S. Supreme Court made a ruling in a patent settlement case which makes clear that the U.S. and EU approach has similarities which might point to a convergence of antitrust perspectives on the patent settlement problem in both jurisdictions. The leading U.S. case concerned a patent settlement between the originator pharmaceutical firm Solvay and the generic Actavis (at that time called Watson pharmaceuticals). Solvay owned a patent for its brand drug AndroGel which was approved for marketing by the U.S. Food and Drug Administration (FDA). Under the U.S. Hatch-Waxman Act Actavis and the pharmaceutical firm Paddock filed a paragraph IV certification for market entry for their generic versions of AndroGel at the FDA and claimed that Solvay's patent would be invalid or the generic would not infringe it. Solvay sued both firms for patent infringement. Despite the FDAs approval of Actavis' generic version of AndroGel the firm entered into a "reverse payment settlement agreement" with the originator. Actavis received "millions of dollars" for delaying the market entry for their generic version of AndroGel and at the same time promoting the original version to doctors instead. The U.S. FTC took action in this case and sued Solvay and Actavis under §5 of the Federal Trade Commission Act. After litigation in District Court as well as the Court of Appeals for the 11th Circuit the U.S. Supreme Court decided on the case (570 U. S. ____ (2013) FTC v. Actavis, Inc.).[32] The FTC, generally being critical towards these agreements by claiming them to be a "win-win" situation for the companies to the detriment of consumers (FTC 2010, p. 1), argued that both firms violated antitrust rules by the attempt to share Solvay's monopoly profits (570 U. S. ____ (2013) FTC v. Actavis, Inc, p. 1). However, the United States Court of Appeals for the Eleventh Circuit ruled against the complaint and found that the agreement did not exclude competition to a larger extent than the scope of the patent implied. The ruling showed the conflicting views of the Court of Appeals on the one hand and the FTC on the other hand. Whereas the court followed the presumption of patent validity and found support for the benefits of the settlement agreement, the FTC saw patent settlements with large value transfer from the originator to the generic as presumptively unlawful rejecting the approach to shield agreements from antitrust scrutiny as long as they are within the exclusionary patent scope (ibid., pp. 2). The Supreme Court in its ruling supported the view of the FTC that a presumption of patent validity is not immunizing patent settlements from antitrust scrutiny even if they stay within the exclusionary patent scope (ibid., p. 8). At the same time, it rejects the FTCs view to conduct a "quick-look" approach in which the defendant had to show countervailing efficiency advantages of the settlement and to hold reverse-payment patent settlements as presumptively unlawful. Instead the court sees the (structured) rule-of-reason approach as appropriate to assess future cases (ibid., pp. 20). Justice Breyer referred to the size and justification of the reverse payment, its anticompetitive effect, as well as to market power derived from the patent and alternatives to the settlement.[33] The Supreme Court Ruling

[31] Important cases are Cephalon, AndroGel, Ciprofloxacin, K-Dur, Opana ER/Lidoderm (FTC Press Releases Pay-for-delay).

[32] Section 5 of the Federal Trade Commission Act (FTC Act) (15 U.S. Code § 45) prohibits "Unfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce (…)".

[33] "In sum, a reverse payment, where large and unjustified, can bring with it the risk of significant anticompetitive effects; one who makes such a payment may be unable to explain and to justify it; such a

infers that a court can use a reverse payment as a proxy for anticompetitive harm. The assessment of the size of the reverse payment particularly depends on the originators expected litigation costs (570 U. S. ____ (2013) FTC v. Actavis, Inc, pp. 19). Post-Actavis there is evidence that courts have interpreted the Supreme Court ruling differently. This is evident regarding the question if non-cash reverse value transfer can constitute an antitrust violation (Thomas 2015, pp. 10). There seems to be some convergence in the sense that the Actavis ruling is interpreted broadly to also include other forms of value transfer which require justification to avoid antitrust liability (Raptis/Delaney, 2015). Also, lower courts face the question regarding the extent to which the rule-of-reason proposed in Actavis is already broadly substantiated (Thomas 2015, pp. 10).

The Supreme Court Ruling made evident that on both sides of the Atlantic patent settlements between originator and generic firms in the pharmaceutical sector can be a competition concern even in case they stay within the patent scope. In both jurisdictions, it is essentially a rule-of-reason analysis which seems to be the policy to assess the anticompetitive nature of settlement agreements. It should however be kept in mind that the rules governing the marketing approval of drugs and the way generics can enter the market are entirely different in Europe and the United States (see section below). In the American discussion post Actavis, it becomes clear that the role of reverse payment is crucial but not sufficient to assess patent settlements. Both the Supreme Court as well as economic and legal scholars emphasize antitrust concerns regarding large reverse payments. However, there are also advocates of the claim that agreements without reverse payments are not necessarily procompetitive (Edlin et al. 2015, pp. 35). And there might be justifications for reverse payments (Edlin et al. 2013, pp. 18). Authors have developed frameworks and conclusions taking specifically into account how reverse payments and justifications for such payments can be assessed (Carrier 2014, Edlin et al. 2015, Kobayashi et al. (2015)). Also, there is a discussion about how to structure the rule-of-reason post-Actavis[34] and to what extent the rule-of-reason in Actavis is not so far away from presumptive illegality of reverse payments, taking into account that the defendant has the burden of proof regarding efficiency effects (Cotter 2014).

6.2 U.S. and EU pharmaceutical sector institutions: What is different?

Two of the questions which remain open are how exactly a rule-of-reason approach should look like and how specifically different regulatory frameworks in the EU and the U.S. should be taken into account. Thus, there is need to assess if and how the interplay of patent law, drug approval rules and pricing and reimbursement schemes, being different in the EU and the U.S., influence the question whether a patent settlement is anticompetitive or not. This involves examining whether rules for patent settlement assessment in both jurisdictions need to be respectively adapted or to which extent mutual learning from each other concerning actual cases is even possible. For patent settlement assessment, the entire institutional framework is relevant (Frank/Kerber 2013, p. 21, Carrier 2009, p. 68, Esposito/Montanaro 2014, pp. 503). Also, we will see that especially in the U.S. marketing authorization and intellectual property are closely interconnected.

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firm or individual may well possess market power derived from the patent; a court, by examining the size of the payment, may well be able to assess its likely anticompetitive effects along with its potential justifications without litigating the validity of the patent; and parties may well find ways to settle patent disputes without the use of reverse payments" (570 U. S. ____ (2013) FTC v. Actavis, Inc, pp. 19-20).

[34] Wang (2014) proposes a three-step test for antitrust authorities including an assessment of the patent holder's market power, justifications for the value transfer and the enforceability of the patent, while a court should take into account countervailing efficiency effects. Miller (2014) proposes five key factors for court assessment of patent settlements post-Actavis which are market power of the parties, less restrictive alternatives for the settlement, a truncated test of patent validity, reverse payments and procompetitive benefits.

6.2.1 Marketing Authorization and Regulatory Protection

The U.S. Hatch-Waxman Act establishes a close interrelation of drug approval through the FDA and the patent law (Fackelmann 2009, p. 353). In the process of filing a "New Drug Applications (NDA)" with the FDA, patents are listed in the "Orange Book". As shown in the Actavis case, generic firms can apply for marketing authorization with an "Abbreviated New Drug Application (ANDA)" at the FDA by filing a "Paragraph IV certification" claiming that patents listed in the Orange Book (U.S. FDA Orange Book) are not valid or not infringed (U.S.Code Title 21 at § 355(j)(2)(A)(vii)). On the other hand, originators can prevent generics for getting this marketing approval for up to 30 months if the patents validity is disputed (FTC 2002, pp. 5). Moreover, the U.S. regulatory framework provides the first generic who files an ANDA under "Paragraph IV certification" with 180 days of marketing exclusivity which in fact excludes other generics from entering (FTC 2002, pp. iv). This however makes patent settlements easier to accomplish since the originator only needs to settle with one generic for the duration of the marketing exclusivity period. At the same time the mechanism to incentive patent challenges might therefore be undermined (Carrier 2009, pp. 70, Frank, Kerber 2013, p. 15). The close interrelation between the Hatch-Waxman regulation and patent settlements becomes evident when looking at a proposal of legal scholars Scott Hemphill and Mark Lemley to address the patent settlement problem by changing the Hatch-Waxman Act itself. They propose to award 180 days of marketing exclusivity only to generic firms that earned it (i.e. depriving settling generics from the 180 days that caused delay and no early entry) (Hemphill/Lemley 2011, pp. 969).[35]

In the European Union there are four very different ways of approving a drug: Firstly by using national proceedings for an authorization only in the specific state; secondly by using a decentralized procedure which allows for a parallel authorization in previously specified member states, thirdly a mutual recognition of previously obtained national authorizations and fourthly by conducting the centralized procedure with an approval via the European Medicines Agency (EMA) to authorize the drug in all member states in the EU at the same time. The decentralized procedure which is basically very close to the mutual recognition procedure may apply to medicines which were not yet approved in the EU. An originator firm may indicate all states where it wishes to obtain marketing approval and use one of these states as a reference in the process. It should be noted that both in the decentralized and the mutual recognition procedures there is only little space for rejecting an application for marketing approval by using a reference state's approval for the specific state (such reasons are mostly related to risks to public health in the specific state) (European Commission 2015b, pp. 15).

For originator and generic approval, it is especially interesting to note that the specific regulations for drug approval include data and marketing exclusivity rules independent of patent protection (European Commission 2015b, pp. 39). Data exclusivity applies for pharmacological tests and clinical trials submitted to the authorizing authority. According to the European Commission Pharma Sector Inquiry, analyzing the costs of originator firms to innovate, the phase of clinical trials (needed to obtain marketing authorization) is the most expensive whereas basic research costs are on a considerably lower cost level (European Commission 2009, p. 56). Thus, the granting of data protection and marketing exclusivity rights additional to patent protection can be seen in the light of the same rational of giving incentives to innovate. Due to regulation proceedings (particularly drug approval) these incentives not only should account for research

[35] Similarly, the existing problem under Hatch-Waxman of multiplying 30-month-stay periods for the same drug by adding new patents to the orange book which continuously blocked generic market access under Hatch-Waxman, was solved by amendments since 2003. Also, provisions for forfeiture of the 180-day exclusivity were inserted (despite not going as far as the Hemhill/Lemley proposal) (Hemphill/Lemley 2011, pp. 959, Medicare Prescription Drug, Improvement, And Modernization Act of 2003; pp. 2448-2460).

and development costs but also for the significant share of investment necessary to obtain marketing authorization for originators. Centrally approved drugs obtain an 8-year data protection period for data submitted for approval at the EMA. At the same time the EMA grants a 10-year period of marketing exclusivity which may be extended to 11 years under certain conditions (Regulation (EC) No 726/2004, Art 14 (11)). Rules in the US grant 5 years of data protection for New Chemical Entities or 3 years for new uses or indications and 180 days of Marketing Exclusivity for a first generic patent challenger on the basis of the Hatch-Waxman Act (FTC 2002, pp. iv, Mossinghoff 1999). These rules are particularly interesting since they can be seen as an innovation incentivizing instrument or as fulfilling a specific purpose as the 180 days of marketing exclusivity which aims at increasing incentives for generics to challenge patents. This takes into consideration considerable costs and risks involved in the process of generic patent challenges as well as the danger that other generics might free ride on a successful challenge and therefore there are too few challenges (Fackelmann 2009, p. 328).

Thus, non-patent intellectual property rights (e.g. marketing exclusivity granted by regulatory authorities) are of high importance in the pharmaceutical sectors both in the U.S. and in Europe. It is likely that firms are taking them into account in their rationale to engage in potentially anticompetitive patent settlements. These forms of parallel intellectual property are similar but not the same in both jurisdictions. How exactly this could influence different analyses of potential competition in an assessment scheme for patent settlements seems to be an important question. Instruments like the 180-days of marketing exclusivity granted to the first generic challenger in the U.S. are interpreted as on one hand incentivizing challenging of patents but also facilitating anticompetitive patent settlements (Janis/Hovenkamp/Lemley 2003, p. 1755, Carrier 2009, pp. 60).

6.2.2 Patent Law and Enforcement

In Europe, in contrast to the U.S., there is no unitary patent (European Commission 2009, pp. 101). As alternative for applying for a patent in each EU country, there is the possibility to register a European patent at the European Patent Office (EPO). The European patent, although examined centrally, is a bundle of national patents which still requires validation in each country the patent should take effect in (ibid., p. 102 at para. 268). The costs for validating and maintaining a European patent is significantly higher than in the U.S. (ibid., pp. 106 at para. 279). Besides national invalidation proceedings, a European patent can be opposed at the EPO within nine month after publication which means that it cannot be enforced before national courts. If the EPO confirms a patent, invalidation is still possible in member states (ibid., pp. 105 at paras. 277, 285). It is evident that national invalidation proceedings differ nationally in Europe and national courts might come to different conclusions when deciding on patent invalidity (ibid. pp. 108). In Germany for example, infringement and invalidation proceedings are separate (bifurcation) in contrast to proceedings other countries have (ibid. p. 108 at fn. 203). In Europe, it is possible to defend against an infringement suit or actively challenge a patent (ibid., pp. 108). Invalidation claims (or non-infringement claims) might consist of proceedings in various member states with different outcomes. Also, difficulties for patent holders to obtain injunctive relief are reported to be different in member states.[36] Thus, because of the scattered European patent system it is more difficult for innovators to register and defend patents. The so-called patent linkage, meaning to directly link marketing approval of a drug to the status of the patent, is different in the U.S. and the EU. Whereas in the U.S., the Hatch-Waxman Act through the Orange Book establishes patent linkage, this is not present in the EU (Rius Sanjuan 2006, pp. 5). As a consequence, under Hatch-Waxman marketing authorization requires to take into account the patent status while generics can request marketing authorization and at the same time claim invalidity. There is however also in Europe a close connection between patent law and marketing authorization

[36] E.g. there is evidence that in the UK injunctive relief is more difficult to obtain than in Belgium (ibid., p. 109 at fn. 205).

when we look at the national level. A good example for the interplay of different factors in the European institutional framework is legislation in Portugal after which a sharp increase in patent settlements was observed. The law requires patent holders to start arbitration proceedings within 30 days in case a generic application for marketing authorization is published to maintain the ability to assert their patent rights (European Commission 2015a, p.8). This shows that settlement agreements are strongly influenced by the institutional setting they are established in and that patent settlement assessment should likewise take this into account. In England, settlements are an essential part of legal disputes (Fischmann 2016, pp. 297). In litigation about patent validity, there exists the possibility that a public representative (protecting the public interest of removing invalid patents) directly interferes in appeal proceedings.[37] Besides the regulatory frameworks there is evidence that differences in patent enforcement might influence the assessment of patent settlements. Authors claim that patent enforcement in Europe is weaker compared to the U.S. Arguments are the existence of limited damages, partial compensation of litigation costs, drug price regulations after generic entry as well as the need to litigate patents or file injunctions in multiple European jurisdictions (Subiotto 2014, pp. 2). For patent holders, this might lead to stronger incentives to settle with generics even if patents are strong (Clancy et al. 2014, pp. 163). In patent settlement assessments, this can be seen as an entirely different justification for reverse payments larger than the originators litigation costs. The idea is that the patent holder essentially tries to countervail the difficulties in enforcing patents and to overcome the shortcoming of the European patent system by including a reverse payment in a settlement, thus protecting innovation incentives. The consequences of an incomplete patent enforcement are referred to as an "invisible value transfer" from the originator to the generic that the patent holder tries to prevent by settling by use of an actual reverse value transfer (ibid., pp. 5). The outcome of such considerations could well be that justifications for reverse payments could be seen in a much wider context including "all irreversible, financial losses (…) even in case of litigation victory" (ibid, p. 7). Similarly, authors point to the existence of strong risk aversion particularly regarding originator's blockbuster drugs which might result in larger reverse payments for reducing uncertainty and maintaining incentives to innovate (Choi et al., 2014, p. 51). It is correct that the European patent system as well as the regulatory framework needs to be taken into account when assessing patent settlements. In particular, there might be good arguments for considering that in Europe it is relatively difficult for innovators to obtain, maintain and enforce patents. But again, this differs from country to country. This then could however justify or require deviating specific assessment schemes for patent settlements compared to the U.S.

6.3 Critical discussions beyond Lundbeck

We find evidence that European and American antitrust authorities have similar approaches in assessing patent settlements by holding reverse payments presumptively illegal (Clancy et al. 2014, p. 170). While the U.S. Supreme Court has rejected this presumption and the "quick-look" approach proposed by the FTC in favor of a rule-of-reason assessment (570 U. S. ____ (2013) FTC v. Actavis, Inc, p. 20), the General Court in Europe affirmed the "by object" assessment in Lundbeck (General Court Case T-467/13 at paras. 175-290). The General Court's decision in Lundbeck however does not preclude other potentially forthcoming decisions in Europe since the Lundbeck decision is based on a very specific combination of factors which are rather unique to the case. In the U.S. compared to Europe there seems to be more discussion around potential justifications for reverse payments. Whereas the U.S. Supreme Court in

[37] Fischmann (2016, p. 303 and p. 304 at fn. 1966 citing case Apimed Medical Honey Limited v. Brightwake Limited) discusses the role of the *comptroller* in English patent litigation appeal proceedings. The specific legal framework leads to the particularity that a previous court decision that a patent is invalid is not automatically repealed by a patent settlement. The *comptroller*, as public representative, can become part of appeal proceedings regarding patent validity and plead for maintaining the invalidity of the patent (ibid., p. 303).

Actavis includes the notion of a "large, unjustified reverse payment" (570 U. S. ____ (2013) FTC v. Actavis, Inc, p. 3) for the assessment of antitrust harm explicitly, the European Commission is not including justifications for such a payment in the guidelines. Instead the notion of a "significant value transfer" is used without further specifications (EC 2014, Technology Transfer Guidelines, pp. 44 at para. 239). Cases suggest however that the Commission examines potential justifications for a value transfer and for the agreements itself (Case at.39226 – Lundbeck, p. 219 at para. 639, Case at.39612 – Perindopril (Servier), pp. 307 at paras. 1331, 1460).[38]

There is a discussion, mostly in legal literature, around the question whether Lundbeck was decided correctly, to what extent this can be compared to the U.S. approach post-Actavis and what this means for future cases. Authors have discussed that the rule-of-reason analysis proposed by the U.S. Supreme Court might be the more sensible approach to adequately assess pro- and anticompetitive effects in patent settlements (Geradin/Ginsburg/Safty 2015, p. 24). Differences are observed between the rule-of-reason analysis laid out in Actavis and the "by object" assessment in Lundbeck, essentially holding reverse payments presumptively illegal (Clancy et al. 2014, pp. 170). There are opinions for an effects-based approach in contrast to the "by object" - standard in Lundbeck (Gallasch, 2015) and critique can be found that the "by object" - standard might not be justified taking into account the complexities around intellectual property in the case. In Europe, the Commission used both the assessment standards of a "restriction by object" (in Lundbeck), in which showing actual anticompetitive harm is not required, and "restriction by effect" (in Servier) involving exactly this requirement. Despite both applied standards differ with respect to the requirement to show actual harmful effects through patent settlement agreements, both cases, Lundbeck and Servier, reflect a detailed analysis of anticompetitive harm. This is supported by the fact that the restriction "by object" assessment in Lundbeck includes also an analysis of efficiency effects regarding Article 101 (3) TFEU. Thus, there is the question how large the actual differences between the U.S. approach post Actavis and the EU assessments really are. Killick/Jourdan (2014) criticize the Lundbeck test of the European Commission as being too vague for a more general application in restriction "by object" assessments of patent settlements. They refer to the rather broad notion of potential competition, a too isolated view on entry restrictions (possibly not taking into account all blocking factors of generic entry) and the strong focus on the reverse payment. They emphasize the difficulty of deriving from the Commission's test in Lundbeck which settlements exactly are anticompetitive and which are not, especially in the absence of the factors specific to Lundbeck. Also, they refer to possible inconsistencies in the Commission's approach with the Lundbeck/Neolab decision which included a reverse value transfer and a restriction of entry but was held unproblematic (Killick et al. 2014, pp. 5, also see fn. 27). In the legal discussion, it is described as being problematic to infer from the reverse payment that a patent would be found invalid, as this depends on many different factors and means predicting outcomes of patent litigation in multiple courts in different countries (Zafar 2014, pp. 208). Other authors have pointed out the many problems and complexities of using the reverse payments as a reliable indicator for finding anticompetitive harm, particularly because there might be good reasons for such a payment (Choi et al. 2014, pp. 49, van der Woude 2009, pp. 193). Authors have mentioned the differences in regulatory frameworks between the EU and the U.S. but also the very similar antitrust assessment schemes, particularly regarding reverse payments (Clancy et al., p. 170). While in the U.S. discussion around patent settlements, the Hatch-Waxman Act is highly relevant, it is not so clear what the differences in the regulatory framework practically means for European rules and how, if at all, they should really be different. Authors point to the possibility that European patent holders might need to settle with more generics (since there is no 180-day marketing exclusivity rule for the first generic challenger like under Hatch-Waxman), but it is also not likely that this changes much in terms of the anticompetitive potential of settlements (Gürkaynak et al. 2014, pp. 156).

[38] These justifications for a reverse payment should then, from an economic perspective, also influence the assessment of patent strength if it is based on the reverse payment as an indicator.

Taking into account on one hand that there are not many differences in actual patent settlement polices in the U.S. and the EU and on the other that the regulatory framework is very different, conclusions are limited and not easy to draw. Commentators from the legal field see uncertainties and open questions in how the EU shapes its patent settlement assessment policies after Lundbeck, although there is not much controversy about the more general arguments. It seems that, on both sides of the Atlantic, the institutional framework of the pharmaceutical sector is not comprehensively incorporated in patent settlement assessment considering the enormous interdependencies thereof. This is true especially for Europe where the overall system of EU- and national rules is more complex. In the U.S., there is some support that the U.S. Supreme Court has paid attention to the institutional frameworks in antitrust.[39] While differences in the institutional framework and also their relevance for patent settlements are clear, this should not preclude that their antirust assessment cannot be similar. It should be noted however that learning from the U.S. is limited to the extent that we need to be aware of the differences in institutions when directly adopting rules, and take these differences into account. Since in the EU actual antitrust rules for patent settlements are still rather general, this seems to be a task which is still in front of us.

7. Safe harbor rules and strong presumptions for patent settlements?

Given the complexity of patent settlement assessment the question can be raised if and under which conditions we should specify more simple rules, meaning safe harbor rules (specifying types of conduct falling outside of antitrust scrutiny) or presumptions for patent settlement assessment. The alternative would be a full rule-of-reason analysis taking into account all relevant effects.

7.1 Are there safe harbor rules for patent settlements in Europe?

From the Commission's policies, it can be derived that both the entry delay and the reverse payment are indicators for anticompetitive harm. We have seen that those indicators are not independent from each other. The importance of the assessment of reverse payments in patent settlements is derived from the difficulty to directly (or technically) assess the strength of the patent and thus whether the agreements fall within its exclusionary scope. The value transfer is used as a proxy for the weakness of the patent and also as a proxy for an entry delay. An assessment of the magnitude of entry delay might therefore directly depend on the magnitude of the reverse payment since this indicates a rather weak patent. We have also seen that assessing value transfers, particularly in cases different than Lundbeck without direct monetary transfers, is not an easy task. The Commission seems to address this problem by looking closely at the likelihood of generic market entry. In cases where settlements are concluded with generics being close to entering the market prior to the agreements, most value transfers might suffice to conclude an antitrust violation. On the contrary, if a value transfer is observed but generics entry was not very likely in the first place, antitrust harm seems not so clear. Following this logic, the assessment of the likelihood of generic entry might to some extent lessen the requirement of exactly assessing the value transfer and to some extent also influence the standards in assessing if reverse payments are problematic. Thus, a reverse payment might be presumptively unlawful if it takes place between close competitors and prevents likely market entry (Monopolkommission 2016, pp. 329 at para. 1072).

Whether there is a safe harbor rule for patent settlements in Europe is not so clear. As we have seen there is no clear safe harbor for no-challenge clauses (European Commission Technology Transfer Guidelines, p. 45 at para. 243), for agreements involving earlier generic market entry (European

[39] "One of the most important antitrust developments in recent years has been the Supreme Court's attention to regulatory regimes in determining the appropriate analysis" (Carrier 2009, p. 68).

Commission 2009, p. 269) or agreements involving no reverse payments (OECD 2014, p. 8). Killick et al. (2014) point out that it seems that agreements without value transfers leading to earlier generic entry without any distortions of the parties' respective assessment of patent strength reflected in the agreements might come close to such a safe harbor. This cannot be seen as a true safe harbor since the Commission only acknowledges that a "pure early entry" agreement "(…) is not likely to attract the highest degree of antitrust scrutiny" (European Commission 2015a, pp.3 at para. 12).

We have seen, in terms of the standards for the assessment of patent settlements the Commission in Lundbeck uses the notion of a "restriction by object" regarding Article 101 TFEU to assess the problematic agreements. In its guidance on "by object restrictions" of competition the Commission relates to the Lundbeck and Fetanyl patent settlement cases as market sharing agreements. These are unlikely to qualify for Article 101 (3) exemptions, according to the Commission (European Commission 2014b). The risk for the Commission that a decision is revoked by a court might well be higher when the standard of a "restriction by object" is used. The General Court in its Lundbeck ruling however confirmed this standard (General Court Case T-467/13 at paras. 175-290). In the Commission's decision in Servier an analysis of "restrictions by effect" was additionally carried out "for the sake of completeness" (Case at.39612 – Perindopril (Servier), p. 376 at para. 1628). Interestingly in Servier, the Commission assessed several settlement agreements as a violation of Article 102 TFEU regarding a unilateral abuse of a dominant position in which originator Servier used its market position to induce generics to delay competition (ibid, pp. 739). Thus, Articles 101 and 102 TFEU may apply simultaneously in patent settlement cases. Although we do not have a clear safe harbor rule and clear presumption in dealing with patent settlements in Europe, we have some indication that competition policy tries to find ways in defining more clearly which settlements are problematic and which are not.

7.2 The error cost-approach in Law & Economics

The economic rationale behind presumptions and safe harbor rules is that it might be beneficial to accept some unprecise rules, which might result in over- or underenforcement of anticompetitive conduct, for the sake of reducing the costs of the antitrust enforcement itself. More generally, making mistakes on the one hand can lead to costs savings on the other (Easterbrook 1984, pp. 14). Decision theory suggests that "rational decision making is based on weighting the benefits and costs of alternative actions" (Beckner III/Salop 1999, p. 45). The question how much costly information should be gathered to make decisions is in itself a decision which is based on the benefits of additional information and additional assessment of this information to reduce decision errors and the investment costs to gather the information (ibid.). The more concrete concept for this rationale in economics is called error cost-approach and aims to "minimize the sum of the welfare costs caused by decision errors of type I ("false positives") and type II ("false negatives") as well as the costs for the application of the rules" (Christiansen/Kerber 2006, p. 3). For example, in case it is possible to identify a case group or types of conduct being anticompetitive almost all of the time, we expect very few mistakes one makes with a per-se condemnation of these types of conduct. As a result, costs can be saved in terms of applying the rule compared to a rule-of reason. At the same time, there might be good arguments to install a safe harbor provision in case there is a high likelihood that a conduct is not harmful to consumers. The savings in regulation costs (in particular administrative costs of regulators, compliance costs for firms including costs of uncertainty) can clearly outweigh the resulting decision errors. The error cost-approach, as underlying concept, has been applied generally to the question how rules should be differentiated. This refers in antitrust particularly to the rule-of-reason vs. per se rules debate in its different applications (Christiansen/Kerber 2006, pp. 8). These rationales in a second step relate to the optimal designs of filters which structure antitrust analysis (Easterbrook 1984, pp. 14). For antitrust this means creating a combination of presumptions, safe harbor - or other types of rules for specific case groups. Defining those case groups based on actual firm conduct is the result of an optimization of decision errors and regulation costs. This can also mean sequentially

sorting pro- and anticompetitive cases (Kerber et al. 2008).[40]

7.3 Towards a structured rule-of-reason approach for patent settlements

While the very general instruments of competition law are capable of addressing the various problems of patent settlements, it should be discussed if true safe harbor rules or strong presumptions are needed. Should we use full-blown rule-of-reason assessment schemes or a structured rule-of-reason? All kinds of different effects are relevant in patent settlement assessment. Identifying these effects, taking them correctly into account and addressing the various tradeoff problems is extremely complex. One answer to this problem might be limiting the analysis by identifying indicators, or case groups, where specific effects seem particularly relevant and conduct the analysis accordingly to avoid taking into account all possible factors in each case. A different answer could be to use a structured rule-of-reason, i.e. to derive presumptions based on what we know from economics as well as empirically. Such a presumption might be rebuttable and could lead to a number of wrong decisions, however can be efficient based on the error cost-approach. Taking into account error costs (costs of wrong decisions in patent settlement cases) and transactions costs (e.g. administrative costs for carrying out a rule-of -reason analysis) Davis (2009) analyzed different rules for the assessment of patent settlements. Following such a theoretical framework there is reason to prefer a ban on reverse payments over a rule-of-reason assessment. This means accepting to ban some procompetitive settlements but to save high amounts of regulation costs.[41] Considering the strong economic argument that payments are instrumental in shifting generic entry to a later point in time, this approach can be supported. It would allow savings of regulation costs compared to a full-blown rule-of reason although it would still require defining and identifying a reverse payment which is a very complex task. From this perspective, there seems to be a good argument to likewise establish a safe harbor rule for patent settlements without any value transfer or where the value transfer cannot be clearly identified, accepting that there might be some anticompetitive settlements among them. The notion of value transfers should however be interpreted broadly, so that firm's ability to find ways to prevent antitrust liability for anticompetitive agreements would be limited. A presumption of illegality of reverse payments combined with a safe harbor rule for pure early entry settlements as a structured rule-of-reason could be a reasonable and more efficient policy approach.

8. Conclusions

The paper studies the European Commission's Lundbeck decision and applies to this case economic insights about the assessment of patent settlements while asking what we can learn more generally for patent settlement assessment in Europe, also from experiences in the U.S. From an economic perspective, the finding of an antitrust violation regarding price effects in Lundbeck can be supported. The case is a clear example of a collusive agreement to delay generic entry. It is correct that the Commission collected evidence regarding Lundbeck's ability to block generic entry through their process patent. It is also correct that it has established a clear connection between the payments and the entry delay and that it has taken into account potential efficiency effects. In case there is clear evidence of limited exclusionary power of intellectual property any settlement agreement with reverse payment and fixed generic entry can

[40] Kerber et al. (2008) apply reasoning based on the error-cost approach to the assessment of competition law cases. Based on this reasoning, they argue that "sequential investigation rules with stop rules" are optimal instead of static per-se rules, full rule-of-reason assessments or rules that lie in between (p.17).

[41] Other authors have also used error cost reasoning in different models and with different results: Woodcock (2016b, pp. 36) implicitly includes error costs for defining a standard to assess patent settlements and advocates for a settlement ban. Edlin et al. (2014) use error cost arguments in their discussion and support of the Actavis patent settlement ruling.

be problematic. Although the result in Lundbeck is the correct one several issues need to be discussed for further dealing with patent settlements:

1.) Although the reverse payment as a proxy for anticompetitiveness is a good one, factors which influence the bargaining of the parties, particularly leading to justifications for a reverse payment, need to be considered. This is especially relevant in cases where authorities are not able to collect evidence about the patents validity but need to use signals from the settlement terms in order to derive the patent strength.
2.) In its decision, the Commission did not conduct an integrated analysis into the interplay of price effects, innovation effects and challenging incentives effects. It is not likely that this would have changed the results in this case, however might be necessary in others. Since there exist tradeoffs and countervailing effects, results might be very different.
3.) The Commission investigated whether the parties in the settlements are potentially competing including the technical means to enter the market. The prospective entry delay therefore is an important argument for finding anticompetitive harm. However, even in case a party in a patent settlement does not have the ability to enter the market, such an agreement can still be problematic if it prevents a patent challenge and affects the potential invalidation of the patent.

Many factors can influence the bargaining outcomes and lead to settlements with or without reverse payments being procompetitive or anticompetitive. This is also true for the specific pharmaceutical sector regulations and characteristics of patent law and patent enforcement in Europe. A sound patent settlement assessment would need to take into account the entire institutional framework and its implications for the settlement and the finding of anticompetitive harm. The error cost-approach can give some support for instituting a strong presumption against reverse payments while maintaining a safe harbor for pure early entry agreements. This currently does not exist in Europe although there is ample indication that policies point in this direction. Especially future empirical research could lead to more insights regarding the specification of case groups which could allow further refining the structured rule-of-reason approach proposed in this essay. If we have more information about the effects of patent settlements in different jurisdictions and under consideration of different factors, we might be able to get closer to really disentangle pro- from anticompetitive settlements.

Appendix

A: Patent Settlements in Europe

	2000 – 2008 (1st half)	2008 (2nd half) - 2009	2010	2011	2012		2013		2014	
					All	Excluding PT-related	All	Excluding PT-related	All	Excluding PT-related
Category A	52%	57%	61%	70%	43%	61%	45%	67%	**49%**	**74%**
Category B.I	26%	33%	36%	19%	51%	30%	47%	22%	**39%**	**7%**
Category B.II	22%	10%	3%	11%	7%	10%	8%	11%	**12%**	**20%**

Note: legislation was adopted in Portugal in 2012, which practically mandates arbitration proceedings between originators and marketing authorisation applicants. When the IPRs are not contested by the generic company, the proceedings are immediately settled. Hence, figures are provided which disregard settlements related to the Portuguese law. It must, however, also be noted that it is not known how many of these settlements would have still taken place absent this law. See footnote 13.

Note: percentages may not add-up to exactly 100% due to the rounding-up of figures.

Source: European Commission, Pharmaceutical Sector Inquiry and first six Patent Settlement Monitoring Exercises

Source: European Commission 2015a, p. 9.

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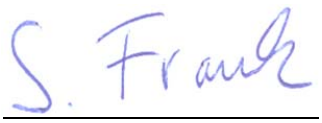

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