Pharmaceutical Reverse Payment Settlements: Presumptions, Procedural Burdens, and Covenants Not to Sue Generic Drug Manufacturers

Catherine J. K. Sandoval
Santa Clara University School of Law, csandoval@scu.edu

Follow this and additional works at: http://digitalcommons.law.scu.edu/facpubs

Part of the Antitrust and Trade Regulation Commons

Automated Citation
Abstract

This Article analyzes recent developments in antitrust law, focusing on agreements between pharmaceutical patent holders and generic drug manufacturers that require a generic manufacturer to delay its market entry in exchange for a payment or other consideration from the patent holder. A predictable consequence of settlements that delay the marketing of a generic drug is that prices for the patented drug will remain higher than if the generic competitor had prevailed in its challenge to the patent’s validity or the patent holder had failed to show that the generic infringed on its patent. Analysis of the legality of these settlements has huge consequences for drug competition, health care costs, the average American family budget, the law, and public policy.

I. INTRODUCTION: PHARMACEUTICAL SETTLEMENTS: PRESUMPTIONS, PROCEDURAL BURDENS, AND COVENANTS NOT TO SUE GENERIC DRUG MANUFACTURERS

The Santa Clara University Computer and High-Tech Law Journal (CHTLJ) invited me to submit this Article to reflect on the Journal’s contributions to antitrust law during the past five years as we celebrate the Journal’s silver anniversary. I congratulate the CHTLJ for its many contributions to the development of the law. The themes explored in CHTLJ articles regarding antitrust and competition law—conceptualizing the purpose of antitrust law, whether to protect consumers and competition or to promote efficiency, and the dichotomous construction of those goals — the
interaction between contract, intellectual property, regulation, and technology, and their effects on competition, innovation, and consumer choice—resonate for scholars, regulators, businesses, the legal community and consumers attempting to resolve antitrust disputes in light of the laws, policies and themes that animate them.

This Article analyzes recent antitrust law developments regarding agreements between pharmaceutical patent holders and generic drug manufacturers that require a generic manufacturer to delay its market entry in exchange for a payment or other consideration from the patent holder (reverse settlement agreements). A predictable consequence of settlements that delay the marketing of a generic drug is that prices for the patented drug will remain higher than if the generic competitor had prevailed in its challenge to the patent’s validity or the patent holder had failed to show that the generic infringed on its patent. Analysis of the legality of these settlements has huge consequences for drug competition, health care costs, the average American family budget, the law, and public policy.

The Federal Trade Commission (FTC) and third-party plaintiffs have alleged that many of these agreements are anticompetitive and violate the FTC Act, which prohibits unfair methods of competition, as well as unfair and deceptive practices affecting interstate commerce. These settlements have also been challenged as a violation of the Section I of the Sherman Act which prohibits “[e]very contract, combination in form of trust or otherwise or conspiracy in restraint of trade or commerce among the several States, or with foreign nations.” The standards of the Sherman Act and the FTC Act are far more nuanced than their broad statutory charges indicate, leaving courts to determine whether the settlement is a per se violation of the antitrust laws, or to balance the potential anticompetitive effects of reverse payment settlements against their alleged pro-competitive benefits under a rule of reason standard, while also considering the effect of the patents on antitrust liability.

Recent court decisions have refused to condemn such settlements as a violation of antitrust laws, instead finding protection for the parties' agreement under the scope of the patent rights at issue.


Lorelei Ritchie’s CHTLJ article observed that contract law is increasingly being used to solve intellectual property disputes, and that while contract law “typically allows parties to devise their own arrangements, there are certain overriding normative restrictions in intellectual property law primarily involving misuse, antitrust, estoppel, and consumer protection.” The multi-billion dollar question remains whether pharmaceutical reverse payment settlements are illegal and violate antitrust and unfair competition laws.

Section II of this article explores the features of the Hatch-Waxman Act (HWA) that authorized the expedited process for Food and Drug Administration (FDA) approval of generic drugs, the abbreviated new drug application (ANDA), and the amendments to the HWA in the Medicare Prescription Drug, Improvement, and Modernization Act (MMA). It contends that the MMA amendments have not achieved their goal of removing barriers to competition and lower drug prices erected and fortified by reverse payment settlements with potential generic competitors, despite high hopes to the contrary.

Section III analyzes the legal principles that have animated review of reverse payment settlements including the debate about the relevant standard of review. That section explores the evolution of reverse payment settlements starting with the In re Cardizem CD Antitrust Litigation [Cardizem] where the Sixth Circuit in 2003 found that the settlement at issue, which prohibited generic drug makers from marketing drugs not implicated by the Name Brand Drug (NBD) holder’s patent, was per se illegal. Since Cardizem, even when such settlements involve payments of a hundred million dollars or more to the potential generic competitor as part of a deal wherein the generic promises to delay its market entry, the legal question in reverse payment cases has increasingly focused on whether the settlement was within the scope of the patent. Courts have given little weight to


examination of the anticompetitive effect of settlements designed to prevent determination of the patent’s validity and scope or to the distinction between cases focusing on whether the generic drug infringed on the patent, as opposed to cases challenging the patent’s validity.

Section IV of this Article argues that recent reverse payment settlement court decisions have inappropriately converted procedural presumptions that the plaintiff challenging a patent’s validity bears the burden of proof of invalidity into a substantive shield against antitrust liability. It argues that this presumption is inapplicable when the key issue is whether the generic drug infringed on the patent since there is no presumption of infringement and the patent holder has the burden of proof to make a prima facie case of infringement. It argues that these presumptions and procedural burdens question the conclusion that settlement agreements should be immune from antitrust liability when they are designed to leave the underlying questions of infringement or invalidity undetermined. It also critiques reverse payment settlement decisions that have used improper standards to shift the burden of proof to the generic drug applicant to prove non-infringement or to limit antitrust liability to cases of sham litigation.

Section V analyzes the imperative of considering whether a reverse payment settlement erects or maintains barriers to third-party competition. It scrutinizes the use of covenants not sue which are often deployed in an attempt to block or delay the ability of generic drug companies to obtain a legal judgment necessary to meet the HWA’s requirements. While the 2007 MedImmune case\(^8\) has blunted the ability of covenants not to sue to block jurisdiction for ANDA filers to seek a declaratory judgment as to the patent’s validity or their generic drug’s non-infringement, such covenants are still deployed to delay or forestall competition through legal challenges to jurisdiction to hear the generic challenger’s case. This Article recommends that Congress require covenants not to sue and similar tactics be reported to the FTC when they are used in an attempt to deny subject matter jurisdiction for substantive determination of patent rights necessary for FDA approval of a generic drug application. It recommends that as part of its examination of the anticompetitive effects of settlements, courts and the FTC should consider the parties’ use of and representations about covenants not to sue and similar devices intended to create delays or deter competition by generic competitors.

Section VI recommends judicial, legislative and FTC scrutiny of the role of covenants not to sue when used to attempt to deprive ANDA filers, particularly subsequent filers, of the ability to challenge a patent’s validity. It suggests additional legislative action to promote both name-brand drug and generic innovation, safeguard competition and protect consumers.

II. THE HATCH-WAXMAN ACT AND THE MEDICARE AMENDMENTS: BALANCING INNOVATION, CONSUMER PROTECTION AND CONGRESSIONAL POLICY TO PROMOTE GENERIC DRUG MARKET ENTRY AND COMPETITION

In order to analyze the antitrust implications of reverse payment settlements, it is necessary to reprise the key features of the FDA drug approval process for generic drugs as provided in the Hatch-Waxman Act. An overview of the 2003 Medicare amendments (MMA), which tried to limit the ability of drug companies to stave off competition through manipulation of the HWA process, reveals why reverse payment settlements and other tactics limit competition, despite the hopes of the MMA’s drafters.

To obtain FDA approval to market a new drug, extensive research, development, testing, and successful clinical trials are required to demonstrate the drug’s safety and efficacy, often requiring years of effort and millions of dollars. Once successful trials are completed, a New Drug Application (NDA) is submitted for FDA approval. The HWA recognized that the drug’s formula or delivery mechanism is often based on one or more patents granted by the Patent and Trademark Office (PTO) and requires the ANDA filer to certify its belief as to the effect of the application on the NDA’s filer’s patents.

The HWA attempted to balance the incentives for new drug innovation, recognizing the substantial investment of time and money

9. HWA, supra note 5.
10. MMA, supra note 6.
13. 21 U.S.C. § 355(b)(2) (A)(i)-(iv) (requiring the generic company to certify one of the following regarding each patent listed in the “Orange Book” where the FDA lists patents submitted by a new drug innovator: (1) no patent information has been filed with the FDA; (2) the patent has expired; (3) the patent will expire on a particular date and approval of the ANDA should be deferred until expiration; or (4) in the opinion of the ANDA applicant, the patent is invalid or will not be infringed by the manufacture, use, or sale of the generic drug).
necessary to obtain FDA approval for new drugs, the right to exclude others from infringing on appropriately granted patents relevant to that drug, the high drug prices characteristic of the period when only the patent holder can market the drug, and the public interest in competition when generic drug makers are allowed to market a bioequivalent medication and substantially decrease drug prices.\textsuperscript{14}

The HWA allows a generic drug maker to file an ANDA to obtain expedited approval to market a generic version of a drug.\textsuperscript{15} To obtain expedited FDA approval under the HWA, the applicant must show that its generic drug performs the same function and contains the same active drug as the NBD,\textsuperscript{16} and is the NBD’s “bioequivalent” in that the drugs are absorbed at the same rate and to the same extent.\textsuperscript{17}

Several antitrust lawsuits have challenged settlements of litigation between a NBD maker which holds patents germane to that drug and a potential marketer of the generic version of a drug wherein the parties agree to delay marketing of the generic drug, often in exchange for cash payments in the millions to the potential generic competitor. In 2008, the Federal Circuit \textit{In re Ciproflaxin Hydrochloride Antitrust Litigation} [hereinafter \textit{Cipro}], analyzed a settlement concerning Bayer’s antibiotic drug Cipro used to treat Anthrax, wherein Bayer and the generic applicant agreed to payments and “side-deals” for marketing and promotional arrangements worth nearly $400 million, in consideration for the generic’s agreement to amend its FDA filing and enter the market years later, but on a date before the relevant patent expired.\textsuperscript{18} Unlike the settlement at issue in \textit{Cipro}, many settlements have included agreements that the generic can seek FDA approval to market its drug before the patent(s) at issue expire, but on a date often years after such competition would have begun if the case had not settled and the NBD’s patent had been found invalid, or the patent holder had not proven that the generic

\begin{flushleft}
14. See Jon Leibowitz, Chairman, Fed. Trade Comm’n, Speech at the Center for American Progress, “Pay for Delay” Settlements in the Pharmaceutical Industry: How Can Congress Stop Anticompetitive Conduct, Protect Consumers’ Wallets, and Help Pay for Health Care Reform (The $35 Billion Solution), (June 23, 2009), http://www2.ftc.gov/speeches/leibowitz/090623payfordelayspeech.pdf (pointing out that the Hatch-Waxman Act resulted in lower drug prices and that when multiple generic versions of a drug are on the market the drug’s price can drop to 90% of the name brand drug); Andrx Pharms., Inc. v. Biowal Corp., 276 F.3d 1368, 1371 (Fed. Cir. 2002).


\end{flushleft}
drug infringed on its patent.

These settlements are often called “reverse payment settlements” because the party claiming its patent was infringed or defending the patent’s validity pays millions of dollars to the generic company it claims infringed the patent to end their litigation and the generic’s challenges to the patent’s validity.\textsuperscript{19} Courts, Congress, regulators, scholars, lawyers, businesses, the legal community, consumers, and consumer advocates have debated whether such practices promote innovation, increase incentives for drug research, and efficiently resolve patent litigation, or harm consumers and unduly limit competition.

Christopher M. Holman’s 2007 CHTLJ article, “Do Reverse Payment Settlements Violate the Antitrust Laws?” argued that “[a]ny attempts to restrict the rights of pharmaceutical patent owners should only be undertaken while bearing in mind the potential harm to incentives for innovation, and ultimately the impact this might have on the next generation of innovative drugs.”\textsuperscript{20} Taking a dimmer view of the effect of reverse payment settlements on innovation and competition, Federal Trade Commission (FTC) Chairman Liebowitz contends that ending such settlements could save \$35 billion in health care costs over the next five years.\textsuperscript{21} Chairman Liebowitz argues that such reverse payment settlements maintain high prices by averting generic competition with a patented drug, unduly allowing the patent holder to charge monopoly profits.\textsuperscript{22}

The HWA recognizes that a generic drug manufacturer is not entitled to FDA approval to market a drug that would infringe on the scope of the name-brand drug holder’s valid patent during the life of that patent.\textsuperscript{23} Nonetheless, the FTC contends that many of these settlements are strategically designed to end litigation that would determine the patent’s validity with the object of limiting competition that preserves the monopoly.\textsuperscript{24} As a consequence, the patent holder is

\begin{enumerate}
\item Holman, \textit{supra} note 11, at 494 (in most patent litigation the alleged infringer pays the patent holder, whereas in “reverse payment” cases the patent holder pays the alleged infringer to withhold the generic drug from the market).
\item Holman, \textit{supra} note 11, at 504.
\item Leibowitz, \textit{supra} note 14, at 1-2.
\item Id.
\end{enumerate}
able to charge high prices for its drugs, a practice the FTC contends constitutes unfair competition and unfair practices in violation of the FTC Act.25

Under the auspices of the Hatch-Waxman Act, a generic drugmaker may challenge a patent by providing a Paragraph IV certification to the FDA that alleges that the patent is invalid or will not be infringed by the generic drug for which approval is sought.26 An ANDA filer under the HWA must notify the NBD maker of its application to the FDA for abbreviated generic approval.27 Receipt of a Paragraph IV certification entitles the patent holder to sue the potential generic drug maker for infringement within 45 days of receipt of that notice.28

Richard Smith pointed out in the CHTLJ that “[i]f the patentee files suit within the 45-day period, the FDA may not approve the ANDA until the expiration of the 30-month period beginning on the date of receipt of notice.”29 This provision gives the patent holder tremendous incentives to sue to delay FDA approval. The 30-month time-period was intended to allow the parties to resolve their litigation claims about the validity of the incumbent’s patent and whether the generic infringes that patent.30

These settlements are often challenged as erecting barriers to entry for subsequent ANDA filers by strategically ensuring that FDA approval timelines for bringing a generic drug to market are not triggered. For drugs where the first applicant filed a Paragraph IV certification before December 2003, before the effective date of the MMA amendments, “the FDA may not approve other generic versions of the same drug until 180 days after the earlier date on which (1) the first company begins commercial marketing of its generic version of the drug, or (2) an appeals court finds the patent(s)

25. Id.

26. Holman, supra note 11, at 505 (citing 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (2000); 21 U.S.C. § 355(j)(2)(B) (2005)). The ANDA applicant may also apply to the FDA by providing a certification under other provisions, notably paragraph III, which certifies that the patent will expire on a particular date and approval of the ANDA should be deferred until that patent’s expiration. 21 U.S.C. § 355(b)(2) (A)(iii). This certification effectively acknowledges that the NBD patent is valid and that the generic drug would infringe on that patent.

27. Id.

28. Id.


subject to paragraph IV certification are invalid or not infringed.”

This creates a 180-day period of exclusivity for marketing of the
generic drug by the entity making the first Paragraph IV filing within
the prescribed time period.

Chaves Mosier and Ritcheson observed that the “[t]he Hatch-
Waxman Act encourages generic manufacturers to challenge weak or
narrow drug patents by providing an “exclusivity period” to the first
company to file an ANDA.” This exclusivity creates duopoly
competition between the patent holder and only one generic drug
maker for a six month time period after the FDA approves the generic
ANDA application. Prices will likely fall after that six month period
expires when other generics enter the market and the competitive field
expands. The FDA found that “the price of a generic drug averages
94% percent of the brand price when there is one generic competitor
on the market, and that the entry of a second generic competitor
reduces prices to 52% of brand price.” Holman argues that patent
holders are motivated to pay settlements not only to protect profits,
but to minimize the risk of an adverse court decision that invalidates
its patent rights.

That exclusivity period creates incentives to enter into
settlements that delay the first Paragraph IV party’s entry into the
market and obstruct marketing by other generic drug makers of the
equivalent drug until that exclusivity period ends. Herbert
Hovenkamp, Mark Janis and Mark A. Lemley point out that reverse
payments may not only stave off generic drug competition from the
other party to the settlement, but also erect barriers to competition
from other generic drug manufacturers whose FDA applications are
blocked by the application of the generic that took the payment to stay
out of the market.

Holman observed that “[i]f the parties to a paragraph IV

an attempt to reduce the ability of a generic to “park” its application and block third parties if
the generic does not bring its product to market. Homan contends those amendments have not
been effective in preventing parking that blocks other potential generics. Holman, supra note 11,
at 505 n. 161 (citing 21 U.S.C. § 355(i)(5)(d) (2005)).
32. Richard D. Chaves Mosier and Steven W. Ritcheson, In re Cardizem and Valley
Drug: A View From the Faultline Between Patent and Antitrust in Pharmaceutical Settlements,
33. Id. at 505 (citing FDA.gov., Generic Competition and Drug Price)
http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm129385.htm.
34. Holman, supra note 11, at 525.
35. Herbert Hovenkamp, Mark Janis & Mark A. Lemley, Anticompetitive Settlement of
litigation reach an agreement pursuant to which the first-filer agrees to delay or forgo market entry, the 180-day generic exclusivity (GE) period will not begin until after the patent litigation is decided in the first-filer’s favor.”  

Holman notes that if “the agreement is a final settlement, resulting in dismissal of the infringement action, the 180-day GE period is never triggered.”  

Thus, the time clock providing 180-days of marketing exclusivity to the first generic to issue a Paragraph IV certification never ends because it never begins. 

Chaves Mosier and Ritcheson argued that “collusion can effectively ‘bottle-neck’ the market for generic drug manufacturers who apply for an ANDA subsequent to the initial ANDA applicant.”  

The exclusion of third-party generics from competition with the patent holder are a consequence of reverse settlement agreements that take advantage of the features of the HWA and the MMA to delay entry and competition by the first ANDA filer, and make a conscious choice to craft their settlement to fortify barriers to entry for subsequent ANDA filers who are not a party to the settlement. 

The FTC’s 2008 complaint challenging Cephalon’s settlement with generic ANDA filers as a violation of the FTC Act alleged that “Cephalon has taken steps to ensure that no court decision will trigger the 180-day exclusivity period, including settling or refusing to litigate with other generic companies that could trigger that exclusivity period.”  

FTC Commissioner (now Chairman) Liebowitz noted that “the 180-day exclusivity, which Congress created to reward generics for entering early, does exactly the opposite: it extends the brand’s monopoly, forcing consumers to pay excessive prices for [drugs] throughout the span of those illegal deals.”  

Chairman Liebowitz’s comments reflect not only his criticisms of the HWA and the failure of the MMA to curb the ability to stall the clock, but also his view that parties are manipulating those rules in an anticompetitive fashion not sanctioned by the rules themselves. 

The MMA required that parties to a reverse payment settlement report such settlements to the FTC, leading to the FTC’s finding that

36. Holman, supra note 11, at 517.  
37. Id.  
38. Id.  
40. Cephalon Complaint, supra note 2.  
42% of reverse payment settlements in 2006 included both compensation to the generic company and a restriction on the generic’s ability to market its product.” 42 The FTC found that 79% of the 45 settlements reported in 2007 for year 2006 involved first ANDA filers. 43 These settlements raise barriers to entry for both the first and subsequent ANDA filers, caused by the settlement terms through which the parties agree not to trigger an event that would compromise the first ANDA’s exclusivity period or start the time clock on that period.

Subsequent ANDA filers can trigger the first ANDA filer’s 180-day exclusivity period by obtaining an appellate court judgment that the relevant drug patent(s) are invalid or not infringed. 44 A subsequent filer has an incentive to bring such an action to remove the roadblock created by the first filer’s settlement with the patent holder. Such a judgment would start the 180-day clock for the first ANDA filer so that even if the generic cannot enter during those six months, it will be able to enter at the end of 180 days without waiting for the expiration of the patent or six months after the first ANDA’s negotiated settlement date with the NBD patent holder.

This same provision creates incentives for patent holders to settle with subsequent ANDA filers or to create procedural roadblocks to a district or appellate court finding of invalidity or infringement that would start the clock for the first ANDA filer. By failing to sue a subsequent ANDA filer for infringement or strategic use of covenants not to sue, the patent holder attempts to stave off an appellate judgment that would trigger the first ANDA filer’s 180-day exclusivity period. Through a covenant not to sue, the patent holder promises not to sue the potential generic competitor. Some patent holders argue that a covenant not to sue deprives the generic of the “case or controversy” necessary for subject matter jurisdiction for the subsequent ANDA filer’s declaratory judgment action. 45 Section V of this Article analyzes the use of these covenants in more depth and the

43. Id.
roadblocks they still create, despite the Supreme Court’s 2007 ruling in *MedImmune v. Genentech* that requires consideration of “all circumstances” to determine jurisdiction in such cases.\(^\text{46}\)

This pattern of settlements, litigation, strategic non-litigation or techniques such as covenants not to sue has indicated that despite optimism that the MMA modifications to the HWA would remove legal roadblocks to first or subsequent ANDA filer’s marketing of the generic drug, the MMA’s goals have not been realized. These roadblocks persist despite the MMA provisions that trigger the first ANDA filer’s loss of its 180-day marketing exclusivity if certain “forfeiture” events occur for agreements subject to the MMA, where the ANDA was filed “after December 8, 2003 and there was no Paragraph IV certification to the listed drug by any other ANDA filer prior to December 8, 2003.”\(^\text{47}\)

The first MMA forfeiture trigger is the first ANDA filer’s failure to market by the later of two events. The first is an event known as the “(aa)” clause date, either 75 days after FDA approval of the first applicant is made effective or 30 months after the date of submission of the first ANDA’s application. The second event is the “(bb)” clause date, 75 days after the date on which at least one of the following has occurred regarding the patents in the Paragraph IV certification: (1) in an infringement action or declaratory judgment regarding the patent in the Paragraph IV certification “a court enters a final decision from which no appeal (other than petition to the Supreme Court for a writ of certiorari) has been or can be taken that the patent is invalid or not infringed,”\(^\text{48}\) or (2) in an infringement action or a declaratory judgment a court signs a settlement order or consent decree that enters a final judgment that includes a finding that the patent is invalid or not infringed, or (3) the patent information submitted in the ANDA application is withdrawn by the applicant.\(^\text{49}\) The forfeiture event triggers only upon the occurrence of the later of the (aa) date or the (bb) date. Even if more than 30 months pass after the ANDA is submitted, satisfying the (aa) clause, the (bb) clause is not triggered if the settlement with the first ANDA filer ends the litigation over the patent’s validity or the generic’s non-infringement. A settlement ensures that no judicial determination initiates forfeiture of the 180-

---

day exclusivity period of the first ANDA under the HWA.\textsuperscript{50}

Matthew Avery observed that "[t]he MMA attempted to remedy bottlenecks in ANDA approval by creating provisions that would lead to forfeiture of the 180-day exclusivity period, but these flawed provisions can be easily avoided by drafting settlement agreements that contain no finding of patent invalidity or non-infringement."\textsuperscript{51} In many settlements, an MMA forfeiture event does not occur because the settlement is silent on infringement of an ANDA filer’s proposed generic drug or on the invalidity of the challenged patent. To combat this practice, Commissioner Liebowitz argued for naming first ANDA filers as defendants if they participated in a reverse payment settlement and refused to relinquish their 180-day exclusivity, blocking other generic entry into the market.\textsuperscript{52}

Forfeiture can also be triggered if the first ANDA holder amends or withdraws its paragraph IV application.\textsuperscript{53} The FDA has interpreted the MMA so that the first ANDA filer is not required to withdraw or amend its application upon settlement with the patent holder, effectively lending the FDA’s regulatory weight to such delays.\textsuperscript{54} Many reverse payment settlements are crafted so that the first ANDA filer does not withdraw its application, failing to trip that start time on that basis.

The settlement evaluated in the \textit{Cipro} antitrust litigation required the first ANDA filer to withdraw its paragraph IV certification of non-infringement or invalidity and file a new application under paragraph III, requiring the first ANDA filer to wait until the relevant patents expired to seek FDA approval.\textsuperscript{55} Similar withdrawals of an ANDA certification would create a forfeiture event under the MMA, opening the door to subsequent ANDA filers’ challenges.

The Federal Circuit emphasized that the \textit{Cipro} settlement with the first ANDA filer did not block third-party filers from challenging the patent.\textsuperscript{56} Thus \textit{Cipro} recognizes that a reviewing court should

\textsuperscript{50} Patel, \textit{ supra} note 44, at 1100-01.
\textsuperscript{52} Leibowitz, \textit{ supra} note 41, at 1.
\textsuperscript{55} \textit{In re Ciprofloxin Hydrochloride Antitrust Litig.}, 544 F.3d 1323 (Fed. Cir. 2008), \textit{cert denied}, 129 S.Ct. 2828 (2009).
\textsuperscript{56} \textit{Id}. 

consider whether the settlement increases or maintains barriers to third-party generic challengers. Other settlements have maintained the blocking position of the first ANDA applicant, a result the Eleventh Circuit in *Schering* and the Second Circuit in *Tamoxifen* attributed to the features of the HWA, rather than as evidence of an anticompetitive agreement in violation of the antitrust laws. 57

Under the MMA, the 180-day exclusivity period of the first ANDA filer can also be forfeited if an appellate court finds in a decision appealable only to the Supreme Court that “an applicant submitting a paragraph IV certification has entered into an agreement with another applicant, or the holder of the NDA or patent owner, in violation of the antitrust laws.”58 This forfeiture event depends on whether the reverse settlement agreement violates the antitrust laws. The question is under what circumstances do such agreements flout the antitrust laws?

As discussed below, the antitrust violation forfeiture provision has not been triggered since the MMA amendments in 2003. Since *Cardizem*, sophisticated parties with billions of dollars at stake have drafted settlements that try to distinguish their features from those condemned in *Cardizem* which precluded the generic from marketing other drugs that did not infringe on the patent at issue. Appellate Courts since *Cardizem* have concluded that the settlements before them were based in large part on the scope of the patent grant and reflected exclusivity conferred by the patent, rather than anticompetitive collusion in violation of the antitrust laws. 59 This reflects judicial reliance on the statutory presumption of a patent’s validity, a presumption Michael Carrier criticizes as converting a procedural burden of proof that the plaintiff must demonstrate invalidity, into a substantive presumption that shields the parties from antitrust liability. 60 This Article calls attention to the legal

---


59. Valley Drug Co. v. Geneva Pharm., Inc., 344 F.3d 1294, 1298-1299, 1303-1304 (11th Cir. 2003) (applying a *per se* standard to find that the settlement of litigation alleging that a generic drug infringed on a NBD’s patent was not a violation on the antitrust laws in light of the exclusionary power of the NBD’s patent), *cert. denied*, 543 U.S. 939 (2004); FTC v. Schering-Plough Corp., 402 F.3d 1056, 1068, 1075; *Tamoxifen*, 466 F.3d at 213-214; *Ciprofloxin*, 544 F.3d 1323.

inapplicability of that presumption where the main issue litigated is whether the generic drug infringes on the patent. The patent holder has the burden of proof of infringement so a settlement delaying the marketing of a non-infringing drug would not be covered by the patent’s exclusionary scope.\(^{61}\)

Additionally, courts since Cardizem have upheld settlements based on the patent’s scope, even when they created or maintained roadblocks to subsequent ANDA filers. The nature of the case method, that a court considers one case at a time based on the facts before it, prevents courts from speculating as to what the patent holder might do to stymie efforts of subsequent ANDA filers to obtain a declaratory judgment as to the patent’s validity or the generic’s non-infringement. This Article emphasizes the need to inquire into the patent holder’s intent to delay resolution of claims by subsequent ANDA filers as part of the analysis of whether the settlement with the first ANDA filer is anticompetitive.

As detailed in sections IV and V below, this Article recommends that reviewing courts should strongly weigh whether the settlement triggers a forfeiture event that opens the door for subsequent ANDA challengers as a factor in determining whether the settlement is anticompetitive or constitutes unfair competition in violation of the antitrust laws or the FTC Act. If the settlement is crafted so that no forfeiture event occurs, the only alternative open for subsequent ANDA filers is to attempt to obtain a declaratory judgment as to the patent’s invalidity or their generic drug’s non-infringement. While Congress hoped that declaratory judgment proceedings authorized by the MMA would clear the way for generic competition, patent holders have tried to foreclose such judgments by covenants not to sue or other litigation tactics designed to deprive the subsequent ANDA filer of subject matter jurisdiction for that declaratory judgment proceeding.

As discussed in section VI, this article recommends that Congress amend the current bills under consideration that would regulate reverse payment settlements by requiring as a factor in weighing whether a settlement should be approved consideration of


the patent holder's representations to the court or the Commission that it will not use covenants not to sue or similar tactics to deprive subject matter jurisdiction for declaratory judgment actions by subsequent ANDA filers. It also recommends that Congress require that patent holders cooperate in obtaining expedited review of declaratory judgments for subsequent ANDA filers, a mandate they must meet for patent litigation with the first ANDA filer. 62

The following section analyzes Cardizem and key reverse payment settlement cases that have declined to find an antitrust violation since Cardizem. It examines the debate in those cases about the appropriate standard of review for reverse payment settlements. It highlights the presumptions of patent validity in cases decided after Cardizem, discusses the analytical shortfalls of that approach, then considers in more detail the effect of settlements on subsequent third-party ANDA filers and the use of covenants not to sue.

III. THE DEBATE OVER THE STANDARD OF REVIEW FOR ANALYZING REVERSE SETTLEMENTS

The Sixth Circuit's decision In re Cardizem CD Antitrust Litigation, found that a reverse payment settlement agreement wherein the patent holder agreed to pay the generic challenger $10 million dollars quarterly to preclude the generic from marketing any version of the Cardizem drug, including those outside the scope of the patent claims, constituted a per se violation of the antitrust laws.63 Cardizem found that the agreements "bolster[ed] the patent's effectiveness," substantiating the case for per se treatment.64 It classified as anticompetitive settlements that expand the patent's scope through an agreement to limit competition beyond the patent's term, or forestall lower prices from generic competition which does not infringe on the patent.65 Cardizem did not, however, explicitly require that the settlement agreement must exceed the scope of the challenged patent in order to find an antitrust violation.

63. In re Cardizem Antitrust Litig., 332 F. 3d 896, 899, 908, n. 13 (6th Cir. 2003). See also Andrx Pharms. Inc. v. Elan Corp., PLC, 421 F.3d 1227, 1235-36 (11th Cir. 2005) (holding that agreement that blocked generic from "ever marketing a generic controlled release naproxen medication 'effectively barr[ed] any generic competitors from entering the market," and was sufficient to state a claim for conspiracy and abuse of monopoly power under the Sherman Act under the Shering-Plough test).
64. Cardizem, 332 F. 3d at 908.
65. Id.
Chaves Mosier and Ritcheson noted that it was "unclear from the decision how much weight the fact that the Agreement blocked non-infringing products had on the court's decision to use the per se rule" to condemn the Cardizem agreements. The agreement's scope was a factor in its illegality, along with evidence of the parties' intent to use the Section IV certification process set forth in the Hatch-Waxman Act to block other generics from entering the market. The Cardizem case suggests that the parties' anticompetitive intent should be weighed, alongside an analysis of whether the agreement bars competition beyond the patent's scope. Yet, Cardizem does not announce a clear path to determine when such agreements are per se illegal.

Subsequent cases have analyzed reverse payment settlements under the rule of reason, focusing their analysis on whether the settlements were commensurate with the patent's scope. The Eleventh Circuit's 2005 Schering-Plough case rejected either a conventional rule of reason or per se standard to analyze the FTC's challenge to pharmaceutical reverse payments settlement, instead adopting a modified rule of reason test that examined: "(1) the scope of the exclusionary potential of the patent, (2) the extent to which the agreements exceeded that scope; (3) and the resulting anticompetitive effects."

Schering held a formulation patent that expired in 2006 for the extended release coating surrounding the unpatented active ingredient in its "K-Dur 20" medication used to treat high blood pressure and congestive heart failure; when faced with potential competition from Upsher, the first ANDA filer, in 1997 Shering promised to pay Upsher $60 million labeled as "initial royalty fees" for the marketing rights to five of Usher's drug products and Upsher's agreement to delay its marketing of a generic version of K-Dur until 2001. In

67. Holman, supra note 11, at 543, 545 (citing Cardizem, 332 F. 3d at 907).
68. FTC v. Schering-Plough Corp., 402 F.3d 1056, 1064 n. 11 (11th Cir. 2005) (citing FTC v. Indiana Fed. of Dentists, 476 U.S. 447, 457 (1986) (other citations omitted) which notes that the rule of reason tests "whether the restraint imposed is such as merely regulates and perhaps thereby promotes competition or whether it is such as may suppress or even destroy competition.").
69. Schering-Plough Corp., 402 F.3d at 1066 (recognizing that the active ingredient in Shering's K-Dur 20 medication, potassium chloride, is commonly used and unpatentable. The litigation focused on the formulation patent for the extended release coating that delivers the drug's active ingredient over a period of time. The Eleventh Circuit noted that generic drug makers could develop their own potassium chloride supplement "so long as the supplement's coating did not infringe on Schering's patent." Schering's agreement with Upsher also involved
1998, Schering entered into a settlement with a subsequent ANDA filer, ESI Lederle (ESI), wherein Schering agreed to pay ESI $5 million representing ESI’s legal fees spent in its litigation with Schering, and an additional $10 million if ESI received FDA approval to market its generic drug and delayed its market entry until 2003, three years before the K-Dur formation patent’s expiration date.70

The Eleventh Circuit emphasized the need to measure the settlement’s anticompetitive effect by comparing it to the patent’s exclusionary scope, but wrongly articulated the standard for proving and evaluating infringement claims stating that “[b]y virtue of its ‘743 patent, Schering obtained the legal right to exclude Upsher and ESI from the market until they proved that the ‘743 patent was invalid or that their products, Klor-con and Micro-K-20 respectively, did not infringe on Schering’s patent.”71 That statement improperly allocates to Upsher and ESI (the “they” ambiguously referenced in the above sentence) the burden of proving that their generic drugs do not infringe on the patent when the law allocates to the patent holder the burden of proving infringement.72

The Eleventh Circuit in Schering-Plough cited FTC complaint counsel’s acknowledgment “that it could not prove that Upsher and ESI could have entered into the market on their own prior to the ‘743 patent’s expiration” as an important factor that reinforced the patent’s a “side deal” to license several other Upsher drugs.

70. Id. at 1060 nn. 6, 8 (noting that Schering’s settlement with ESI also involved ESI’s agreement to license two of ESI’s drugs to Schering).

71. Id. at 1066-1067.

72. The patent holder, Schering, not the generic drug maker, bears the burden of providing that the generic drugs infringed on their patent so the Eleventh Circuit’s evaluation of the settlement at issue in Schering-Plough is based on a legal error. See Bristol-Myers Squibb Company v. Andrx, 343 F. Supp. 2d 1124, 1133-1134 (“In order for a product to literally infringe a patent claim, the patentee must prove by a preponderance of the evidence that the accused product includes elements that are literally identical to each and every limitation of the patent claim.”) (citing Biovail Corp. Int’l v. Andrx Pharrms., Inc., 239 F.3d 1297, 1302 (Fed. Cir. 2001) (other citations omitted)). Bristol-Myers Squibb rejected the NBD patent holder’s claim that a potential generic competitor, Andrx, who filed under the Hatch-Waxman Act, infringed on its patent. Bristol-Myers Squibb Company v. Andrx, 343 F. Supp. 2d 1127. See also, Johnson & Johnson Vision Care Inc. v. Ciba Vision Corp., 634 F. Supp. 2d 1293 (M.D.Fla. 2008) (“To prevail on infringement, the patentee ‘must establish by a preponderance of the evidence that the accused device infringes one or more claims of the patent either literally or under the doctrine of equivalents.’”) (citing Advanced Cardiovascular Sys., Inc. v. Scimed Life Sys., Inc., 261 F.3d 1329, 1336 (Fed. Cir. 2001) (other citations omitted)); Ajinomo To Co., Inc. v. Archer-Daniels-Midlands Co., 228 F.3d 1338, 1347 (Fed. Cir. 2000), reh’g and reh’g en banc denied, (Nov. 14, 2000), cert denied, 532 U.S. 1019 (2001) (patent holder bore the burden of establishing that the other party’s manufacturing process infringed on its patents); SmithKline Diagnostics, Inc. v. Helena Lab. Corp., 859 F.2d 788, 889 (Fed. Cir. 1988) (citing the patent holder’s burden of proving literal infringement).
strength and validity. Yet, a non-infringing drug could enter the market before the expiration of the NBD maker’s relevant patent. The Eleventh Circuit’s conclusion inappropriately shifts the burden of proving patent infringement to the FTC. It conflates patent infringement claims with allegations of patent invalidity as evidenced by the Eleventh Circuit’s statement that “without any evidence to the contrary, there is a presumption that the ‘743 patent [the time-release formulation patent implicated by the generic filer’s application] is a valid one, which gives Schering the ability to exclude those who infringe on its product.” The question is whether the generic drug infringed on Schering’s patent, an issue for which Schering bore the burden of proof.

Additionally, the Eleventh Circuit emphasized that “there has been no allegation that the ‘743 patent itself is invalid or that the resulting infringement suits against Upsher and ESI were “shams.” This novel basis for refusing to find antitrust liability in a reverse payment settlement case, unsupported by any legal authority, purports that the FTC must prove that the patent holder’s infringement claim was invalid or a sham for anticompetitive behavior in order to find that the settlement violated the FTC Act. The “sham” standard is a high standard requiring that the litigation be “objectively baseless” to lose its entitlement to antitrust immunity, recognizing the role of litigation in seeking redress from the government. The

73. Schering-Plough Corp., 402 F.3d at 1068.
74. Id. In a lawsuit brought by private plaintiffs challenging the same settlement agreements at issue in Schering-Plough, the plaintiffs alleged that the generic manufacturer “agreed not to enter the market with any generic competitor drug, irrespective of whether it infringed the patent,” leading the district court to conclude that “[t]hese agreements, as alleged, grant rights to Schering in excess of what is granted by the [relevant] patent alone.” In re K-Dur Antitrust Litig., 338 F. Supp.2d 517, 532 (D.N.J. 2004). In Schering-Plough, the Eleventh Circuit characterized the parties’ settlement which covered “any sustained release microencapsulated potassium-chloride tablet” as an “ancillary restraint” of trade necessary to “define the parameters of the agreement and to prevent future litigation over what may or may not infringe upon the patent.” Schering-Plough Corp., 402 F.3d at 1072 (citing Rothery Storage & Van Co. v. Atlas Van Lines, 792 F.2d 210, 224 (D.C. Cir. 1986)). Yet, this settlement precludes the generic ANDA applicants from marketing any potassium-chloride tablet that uses a microencapsulated sustained release formula, even if that formula did not infringe on Schering’s patent. The Eleventh Circuit’s characterization of the settlement’s scope as an “ancillary restraint” is particularly curious in light of its emphasis that “[i]t is uncontested that potassium chloride is the unpatentable active ingredient in Schering’s brand-name drug K-Dur 20.” Schering-Plough Corp., 402 F.3d at 1067. Schering’s patent “only covers the individualized delivery method (the sustained release formula).” Id. Moreover, it only covers Schering’s particular sustained release formula, not microencapsulated sustained release formulas in general for delivering an unpatented active ingredient.
75. Schering-Plough Corp., 402 F.3d at 1068.
76. Prof’l Real Estate Investors v. Columbia Pictures Indus., 580 U.S. 49, 60-61 (1993);
unprecedented application of the “sham” standard to protect infringement settlements between NBD makers and potential generic competitors from antitrust scrutiny fails to account for the legal allocation of the burden of proof to the patent holder to show infringement. This burden of proof recognizes the distinction between challenges to a patent’s validity that allocates to the plaintiff the burden of proving the patent was invalid in light of the patent office’s decision to grant a patent, as opposed to the requirement that the patent holder must present substantial evidence to support its burden of proof that the generic infringes on that patent.\footnote{In re Terazosin Hydrochloride Antitrust Litigation, 352 F.Supp.2d 1279, 1302 (S.D.Fla. 2005) (recognizing that a party challenging a patent’s validity must prove invalidity by clear and convincing evidence). Cf. SmithKline, 859 F.2d at 889 (citing the patent holder’s burden of proving literal infringement by a preponderance of the evidence).}

The Second Circuit in its 2006 analysis of the \textit{In re Tamoxifen Citrate Antitrust Litigation} concerning a NBD manufacturer’s allegation that an ANDA applicant’s generic drug violated its patents for the Tamoxifen, the most widely prescribed drug to treat breast cancer, echoed \textit{Schering-Plough’s} emphasis on the sham litigation line between permissible patent protection and anticompetitive activity.\footnote{In re Tamoxifen Citrate Antitrust Litigation, 466 F.3d 187, 193, 213-214 (2nd Cir. 2006), cert. denied, 551 U.S. 1144 (2007).} The Second Circuit emphasized in \textit{Tamoxifen} that unless the settlement extended the NBD maker’s monopoly beyond the patent’s scope, the chief issue is whether the underlying infringement lawsuit was “objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits.”\footnote{Id. at 213. The Tamoxifen majority contested the dissent’s characterization of this statement as requiring a showing that the underlying litigation was a sham as a basis for antitrust liability. \textit{Id.} at n.27 (“We do not… think that there is a “requirement” that antitrust plaintiffs ‘must show that the settled litigation was a sham, i.e., objectively baseless, before the settlement can be considered an antitrust violation…’ There is no such requirement.” “A plaintiff need not allege or prove sham litigation in order to succeed in establishing that a settlement has provided defendants ‘with benefits exceeding the scope of the tamoxifen patent.’”).} Judge Pooler’s dissent distinguishes between antitrust immunity for filing litigation or using administrative procedures unless the litigation or filing itself is a sham, as compared to the Tamoxifen majority’s application of the sham doctrine to define “antitrust liability in the first instance.”\footnote{Tamoxifen, 466 F.3d at 224-225 (Pooler, J., dissenting). Judge Pooler observed that “[a]lthough Zeneca’s [the NBD patent holder] original suit was likely protected under the standard set out in Professional Real Estate Investors, it does not necessarily follow that the settlement of that suit should be judged on the same grounds.” \textit{Id.} at 225.} Even if the patent holder’s infringement suit was not

\begin{footnotesize}
\begin{itemize}
\item \footnote{Eastern R.R. President’s Conference v. Noerr Motor Freight Inc., 365 U.S. 127, 137-38 (1961).}
\item \footnote{In re Terazosin Hydrochloride Antitrust Litigation, 352 F.Supp.2d 1279, 1302 (S.D.Fla. 2005) (recognizing that a party challenging a patent’s validity must prove invalidity by clear and convincing evidence). Cf. SmithKline, 859 F.2d at 889 (citing the patent holder’s burden of proving literal infringement by a preponderance of the evidence).}
\item \footnote{In re Tamoxifen Citrate Antitrust Litigation, 466 F.3d 187, 193, 213-214 (2nd Cir. 2006), cert. denied, 551 U.S. 1144 (2007).}
\item \footnote{Id. at 213. The Tamoxifen majority contested the dissent’s characterization of this statement as requiring a showing that the underlying litigation was a sham as a basis for antitrust liability. \textit{Id.} at n.27 (“We do not… think that there is a “requirement” that antitrust plaintiffs ‘must show that the settled litigation was a sham, i.e., objectively baseless, before the settlement can be considered an antitrust violation…’ There is no such requirement.” “A plaintiff need not allege or prove sham litigation in order to succeed in establishing that a settlement has provided defendants ‘with benefits exceeding the scope of the tamoxifen patent.’”).}
\item \footnote{Tamoxifen, 466 F.3d at 224-225 (Pooler, J., dissenting). Judge Pooler observed that “[a]lthough Zeneca’s [the NBD patent holder] original suit was likely protected under the standard set out in Professional Real Estate Investors, it does not necessarily follow that the settlement of that suit should be judged on the same grounds.” \textit{Id.} at 225.}
\end{itemize}
\end{footnotesize}
a sham, the assertion that the lack of sham litigation confers antitrust immunity confuses the basis for the antitrust claim. The FTC did not challenge the infringement litigation as an anticompetitive sham; what was at issue was whether the settlement of that litigation that involved the NBD’s payment of millions to the potential generic competitor and the generic’s promise to delay its market entry violated the antitrust laws. A patent holder is not entitled to prevent market entry by products which do not infringe on its intellectual property rights. The sham litigation standard fails to comport with the potential exclusionary scope of patent rights or with antitrust jurisprudence.

_Tamoxifen_ rejected _Cardizem_’s suggestion that _per se_ liability attached to reverse settlement agreements, and followed the Eleventh Circuit’s lead in _Schering-Plough_ in examining whether the agreements exceeded the scope of the patents at issue.81 _Tamoxifen_ distinguished the _Cardizem_ case on the facts emphasizing that unlike the settlement agreement at issue in _Cardizem_, the _Tamoxifen_ agreement did not restrain the introduction of non-infringing products outside of the patent’s scope.82 The Second Circuit also noted that the _Tamoxifen_ agreement between the patent holder and the generic filer did not prevent other generics from challenging the incumbent’s patents, unlike the agreement scrutinized in _Cardizem_.83 The settlements in _Schering_ and _Tamoxifen_ were found to track the patent’s scope, although the litigation never determined whether the patent was valid or infringed.

_In re Ciproflaxin Hydrochloride Antitrust Litigation_ [hereinafter _Cipro_], the Federal Circuit in 2008 reviewed the agreement between patent holder Bayer and several generic manufacturers whereby the generic challenger Barr agreed to amend its ANDA application with the FDA to drop its challenge to the validity of Bayer’s patent in exchange for Bayer’s payment of $398.1 million and other “co-promotion” agreements with Barr.84 The agreement also allowed Barr to market its generic six months before the relevant Bayer patent

81. _Id._ at 213-214.

82. _Id._

83. _Id._ at 214-215 (the settlement, which followed the district court’s determination that NBD Zeneca’s patent was valid, opened Zeneca’s patent “to immediate challenge by other potential generic manufacturers, which did indeed follow spurred by the additional incentive (at the time) of potentially securing the 180-day exclusivity period available upon a victory in a subsequent infringement lawsuit, since by vacating the district court judgment and amending its ANDA to remove its paragraph IV certification, Barr appeared to ensure (under procedures in effect at the time) that it was not eligible for the exclusivity period”).

84. In _re Ciprofloxacin Hydrochloride Antitrust Litigation_, 544 F.3d 1323, 1328-29 n.5, _reh’g en banc denied_, (Fed. Cir. 2008).
expired, a factor the Federal Circuit cited in finding the agreement did not violate the antitrust laws.\textsuperscript{85}

The Federal Circuit in \textit{Cipro} emphasized that this settlement did not create a bottleneck to other generic challengers because Barr withdrew its paragraph IV application that challenged the validity of Bayer’s patent, opening the door for subsequent generic manufacturers to take a shot at Bayer’s patent.\textsuperscript{86} Following Barr’s amendment of its ANDA application, each of four generic challengers lost its case contesting the validity of Bayer’s patent, a fact the Federal Circuit emphasized in upholding the settlements as within the scope of Bayer’s patent.\textsuperscript{87}

In \textit{Cipro} the Federal Circuit sought to unify the goals of antitrust and patent analysis declaring that “[t]he essence of the inquiry is whether the agreements restrict competition beyond the exclusionary zone of the patents.”\textsuperscript{88} It also agreed with the \textit{Tamoxifen} and \textit{Schering-Plough} conclusions that “in absence of evidence of fraud before the PTO or sham litigation, the court need not consider the validity of the patent in the antitrust analysis of a settlement agreement involving a reverse payment.”\textsuperscript{89} Holman suggests that a consensus is emerging “that will find a violation of the antitrust laws only in cases where the challenged agreement contains restrictions on competition that exceed the exclusionary potential of the patent.”\textsuperscript{90} This observation fails to take into account the distinction between infringement cases and litigation over the patent’s validity, since exclusion of a non-infringing drug is not within the patent’s scope.

The Federal Circuit’s \textit{Cipro} decision emphasized that a patent is presumed to be valid and confers the right to exclude others. The statute it cites for this presumption, 35 U.S.C. §282, allocates the burden of proof to the plaintiff challenging the patent’s validity, showing this presumption is rebuttable.\textsuperscript{91} This rebuttable, procedural presumption of validity is not a statutory declaration of antitrust immunity. Moreover, this presumption does not imply that infringement claims are assumed to be valid. Indeed, the patent holder bears the burden of proof to make a prima facie case of

\begin{itemize}
\item \textsuperscript{85} \textit{Id.}
\item \textsuperscript{86} \textit{Id.}
\item \textsuperscript{87} \textit{Id.} at 1329, 1339-1340.
\item \textsuperscript{88} \textit{Id.} at 1336.
\item \textsuperscript{89} \textit{Id.}
\item \textsuperscript{90} Holman, supra note 11, at 541 (citing Valley Drug v. Geneva Phanns, Inc., 344 F.3d 1294, 1312 (11th Cir. 2003)).
\item \textsuperscript{91} 35 U.S.C. § 282 (2006).
\end{itemize}
infringement.  

IV. PATENTS ARE PRESUMED TO BE VALID; SHOULD A BURDEN OF PROOF BE TRANSFORMED INTO A SUBSTANTIVE PRESUMPTION THAT THE SETTLEMENT'S EFFECTS ARE NOT ANTICOMPETITIVE?

In the *Cipro* case the Federal Circuit emphasized that the relevant patent statute, 35 U.S.C. §282, states that "patents shall be presumed valid." The Federal Circuit cited this statutory presumption as a key factor in determining that a settlement that reflects the patent's scope is protected by the ability to exclude others from infringement on the patent. The Federal Circuit argues that such exclusion effectively stems from the patent laws, not from an anticompetitive agreement.

Analysis of this statute clarifies that it allocates to the plaintiff the burden of proof to show the patent is invalid. The presumption of a patent's validity is rebuttable. A 2002 FTC report revealed that in cases where the litigation was not settled before trial, the generic applicant prevailed in 73% of the challenges under Hatch-Waxman that went to trial. The success of generics in challenging the validity of NBD maker patents or showing that their drug would not infringe emphasizes that the presumption of patent validity is only a contestable presumption.

*Cipro* transforms this procedural allocation of the burden of proof into a substantive presumption of validity that shields a patent settlement from an antitrust claim if the settlement roughly tracks the scope of the challenged patent. Carrier emphasizes that patent holders are not entitled to rely on the presumption of patent validity "as substantive evidence in preliminary-injunction proceedings." In

---


94. *Id.*, at 1332-34 ("Thus, the essence of the agreement was to exclude the defendants from profiting from the patented invention. This is well within Bayer's rights as the patentee.").


98. Carrier, *supra* note 60, at 64.
Cipro, the Federal Circuit did not cite its own precedent that previously explained that “the presumption is a 'procedural device' for allocating burdens of production and persuasion at trial, not 'evidence which can be 'weighed' in determining likelihood of success' at the preliminary injunction stage.” Without acknowledging this distinction, the Federal Circuit improperly converted this procedural device that allocated the burden of proof for patent invalidity claims into a presumption that the settlement’s constraints on competition arise from the patent’s scope, rather than anticompetitive effects or animus.

Reliance on a presumption of patent validity to approve a reverse payment settlement gives no weight to the fact that the settlement ceases the litigation about the patent’s validity so it is unknown whether the plaintiff would have carried its burden of proof. Carrier argues that “the presumption should be entitled to the least amount of deference in situations in which the parties enter agreements that prevent validity from even being challenged.” Carrier emphasizes “if the patent is not valid, there is no scope at all.” An agreement to limit competition based on an invalid patent would not rest on patent law but fall squarely within the prohibitions of the Sherman and FTC Acts.

Moreover, the Cipro case’s emphasis on the presumption of the patent’s validity as a factor in upholding the settlement does not apply where the main issue in contention is whether the generic drug infringed on the patent. There is no presumption of infringement. The patent owner alleging infringement bears the burden of proof that the other party infringed on its patent by showing, for example, that the manufacturing process was covered by the challenged patent. Once the patent holder has established a prima facie case of infringement, the burden shifts to the defendant to show that its conduct or process did not infringe on the patent.

Cipro’s stress on the presumption of the patent’s validity

100. Carrier, supra note 60, at 64.
101. Id. at 66.
102. Ajinomoto Co., Inc. v. Archer-Daniels-Midlands Co., 228 F.3d 1338 (Fed. Cir. 2000); SmithKline Diagnostics, Inc. v. Helena Lab. Corp., 859 F.2d 878, 889 (Fed. Cir. 1988) (holding that the patent owner has the burden of proving literal infringement and must meet its burden by a preponderance of the evidence).
103. Ajinomoto, 228 F.3d at 1347.
emphasizes that the generic bore the burden of proving that the patent was invalid. The allocation of the burden of proof to the patent holder to prove infringement should lead a court to reject a reverse payment settlement and side-deals in cases with strong evidence that the generic drug did not infringe on the patent. The patent holder’s failure to carry its burden of proof to show infringement should take the settlement out of the umbrella of the patent’s scope, opening the door to antitrust claims.

In evaluating whether a settlement of an infringement claim is anticompetitive, the court should give strong weight to Congress’ goal in passing the HWA and the MMA amendments: to balance innovation, competition, and consumer welfare by promoting generic entry and competition.\(^{104}\) Cipro’s logic suggests that absent a finding that the patent holder has met its burden of proof to make out a prima facie infringement case, the parties cannot shield their reverse payment settlement from antitrust claims by relying on the scope of the patent in an infringement case.

The FTC’s 2008 case against Cephalon demonstrates the pitfalls of assuming patent validity and that the generic drug infringes on the patent as a defense to FTC Act or antitrust violations. In its complaint characterizing Cephalon’s settlement with its generic challengers as anticompetitive, the FTC presented evidence that Cephalon’s CEO told investors prior to its settlement with the generic challengers that it expected profits to decline with imminent generic entry.\(^ {105}\) Prior to the settlements, Cephalon’s CEO forecast on an earnings conference call that the company assumed that “‘generic versions of mondafinil [the patented drug at issue] enter the market midyear.’”\(^ {106}\)

Cephalon’s patent covering the mondafinil compound expired in 2001 and the only remaining patent on the drug covers “a formulation of mondafinil consisting of a specified distribution of small particles” which will expire in 2015.\(^ {107}\) The FTC cited evidence that “a consultant advised Cephalon in 2002 that ‘all the generic drug companies know... the [Particle Size Patent] may be easily circumvented’ by manufacturing their products to contain a

105. Cephalon Complaint, supra note 2, at ¶ 48.
107. Cephalon Complaint, supra note 2, at ¶¶ 32-34.
distribution of monodafinil particles sizes different than that covered by Cephalon's patent. This advice highlights the risk, even the likelihood that generic drugs using a different delivery mechanism than Cephalon’s patent would not infringe on that patent.

In late 2005 through early 2006, Cephalon entered into agreements with four potential generic drug manufacturers, all of whom qualified as the first ANDA filer, for $200 million in purportedly independent business transactions to settle Cephalon’s infringement claims. Cephalon’s CEO boasted to investors that because of the settlements “we were able to get six more years of patent protection. That’s $4 billion in sales that no one expected.” The FTC argues that Cephalon believed its infringement claim was weak, that the settlement was not within the patent’s scope, and violated the FTC Act.

FTC Commissioner Rosch argues that these facts distinguish the FTC’s case against Cephalon from Tamoxifen and Schering-Plough. Cephalon may argue that this settlement merely reflected its assessment of the risk that a court would find that the generic did not infringe on the one remaining relevant patent related to the drug’s delivery mechanism. Risk assessment is not, however, a defense to an antitrust claim. Neither should patent law shield the parties from antitrust liability where the evidence indicates that one or both parties had a strong belief that the patent holder would not carry its burden of proof that the generic drug infringed on its patent.

FTC Chairman Leibowitz argues that “the incentive to pay a generic to abandon its patent challenge is greatest for the weakest patents.” The patent holder’s weak infringement case in Cephalon supports this observation. The settlement also prevented determination of whether the patent holder’s infringement allegations were a sham that would provide a separate basis for antitrust liability. In light of these facts, the reviewing court should consider

108. Id. at ¶ 35.
109. Id. at ¶ 56.
111. Cephalon Complaint, supra note 2, at ¶ 83 (citing Cephalon CEO’s statements to investors that “We’ve got Provigil [the NBD at issue] through 2012. You know the history of the company. We didn’t expect to be there.”).
112. Rosch, supra note 24, at 22.
113. Leibowitz, supra note 14, at 6.
114. See Teva Phanns. USA, Inc. v. Abbott Labs., 580 F. Supp. 2d 345, 364 (D. Del. 2008) (holding that “a jury could find defendants’ infringement allegations objectively baseless, such as to render the capsule litigation a sham.”).
Cephalon’s public statements, actions, and the strength of the generic’s claim that their drugs did not infringe to measure the anticompetitive effect of the settlement. Unlike the Federal Circuit’s Cipro case, this analysis may not rest on the patent’s validity since infringement, not validity, is the chief patent issue and the burden of proof is on the patent holder to show infringement.

In another FTC complaint emphasizing the patent holder’s weak evidence of the generic’s patent infringement, in January 2009, the FTC filed suit in the Central District of California contending that the agreement between Solvay Pharmaceuticals’ (Solvay) and generic drug makers Watson Pharmaceuticals, Paddock Laboratories and Par Pharmaceutical Company to delay generic competition to Solvay’s testosterone-replacement drug AndroGel until 2015 violates Section 5 of the FTC Act. In *FTC v. Watson*, et. al., the FTC and the Attorney General for the State of California filed a complaint against Solvay and the generics with whom it reached an agreement to delay generic entry into the drug market.

The complaint alleges that generic drug applicants Watson and Paddock, in partnership with Par, filed applications with the FDA to market generic versions of AndroGel, and by early 2006 the FDA approved Watson’s application to market its generic drug. After Watson and Paddock announced their plans to sell generic AndroGel, Solvay sued the generic companies alleging infringement of the AndroGel patent. The generics defended against Solvay’s suit contending that the generic products did not infringe on Solvay’s patent, that Solvay’s patent was invalid, and that Solvay improperly withheld information from the U.S. Patent Office.

The FTC alleges that in settlement of their litigation claims, the parties agreed to withhold their generic products from the market for nine years until 2015, and to promote AndroGel as a means of paying the generics for keeping their lower cost drugs out of the market. The AndroGel patent expires in 2021, a fact the defendants highlight to characterize the settlement as pro-competitive because it accelerates generic competition to a date six years before the relevant

---

116. *Id.* at ¶ 2.
117. *Id.* at ¶ 3.
118. *Id.*
119. *Id.* at ¶ 4-6.
Holman noted that most reverse settlement agreements do not require the generic to stay out of the market for the full term of the patented drug, but "involve a negotiated market entry date for the generic product that... typically occurs later than would have likely occurred if the generic company had prevailed in the patent dispute, i.e., the parties split the remaining patent term." 121 Holman argues that such settlements "can promote competition by providing a guaranteed reduction in the effective patent term that would not have occurred absent the patent challenge." 122 He acknowledges, however, that a successful challenge to the patent might have resulted in earlier entry of the generic drug and opened the field to more competition. 123

The FTC and the State of California contend that despite generic entry before the patents expired in the FTC v. Watson case, the agreement maintains high drug prices in the meantime based on a weak claim of patent infringement, thwarts public policy to encourage competition by generic drugs, violates unfair competition laws, and federal and state antitrust laws. 124 The FTC conducted a study of settlements reached before 2004 and found that settlements involving reverse payments "delay generic entry by 17 months more than settlements without payments." 125 This delay is particularly untenable when based on a weak or dubious patent infringement claim.

In FTC v. Watson, the FTC emphasized that the potential generic entrants "amassed substantial evidence that their generic products did not infringe [Solvay's] formulation patent and that the patent was invalid and/or unenforceable." 126 The FTC noted that Solvay and Besins (from whom Solvay licensed the U.S. rights for Androgel) bore the burden of proving that the generic formulas infringed on their patents, and that they had not met that burden when the litigation ended. 127

The FTC v. Watson case also challenges co-promotion arrangements that effectively allow the generic to share some of the original patent holder's profits from the sale of the patented drug.

120. Id. at ¶ 4-6, 44.
121. Holman, supra note 11, at 494-95.
122. Holman, supra note 11, at 495.
123. Id.
124. FTC v. Watson Complaint, supra note 115, at ¶¶ 6, 93, 97, 100-02, 107, 109, 113, 116, 121.
125. Leibowitz, supra note 14, at 7-8.
126. FTC v. Watson Complaint, supra note 115, at ¶ 86.
127. Id. at ¶ 40, 91.
while the generic version remains out of the market. Par also agreed to act as a "backup manufacturer" for AndroGel, an agreement the FTC alleges was designed to compensate Par for not entering the market. The FTC characterizes these agreements as means to disguise the "pay for delay" nature of the settlement.

The court will have to determine whether the Watson co-promotion arrangement is an "ancillary agreement" of the type the Eleventh Circuit upheld in Schering-Plough as an independent business transaction. The FTC contends that the payments to Watson and Par are not ancillary or independent business transactions without anticompetitive motive or effect, alleging that the value of the Solvay's promised payments far exceed the services provided and depart from industry standards.

The FTC's 2008 Cephalon complaint also involves "side-deals" with the patent holder and four generic first-ANDA filers worth over $200 million. Scott Hemphill analyzed public data on contracts between generics and patent holders and found such "side deals" or "independent transactions" rare except in cases of reverse payment settlements. Hemphill's findings add to the chorus of skepticism about the independent nature of these transactions with likely competitors.

The large amount of money and other consideration exchanged in these settlements has generated criticism about the suggestion that they are tailored to reflect the patent's scope or independent side deals. Chaves Mosier and Ritcheson argue that settlement payments that exceed expected litigation costs or that facially exceed the patent grant should be presumed *per se* illegal.

The Department of Justice (DOJ) in its 2009 brief filed in the Ciprofloxacin case pending in the Second Circuit urged adoption of a standard whereby pharmaceutical settlements should be treated as

128. *Id.* at ¶¶ 5, 62, 66, 77.

129. *Id.* at ¶ 74.

130. *Id.* at ¶ 81.

131. Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1073, 1076 (11th Cir. 2005).


133. Hemphill, An Aggregate Approach to Antitrust, supra note 110, at 666 ("Outside of settlement, brand-name firms seldom contract with generic firms for help with the activities that form the basis of side deals...with the exception of authorized generic arrangements" through which the patent holder authorizes one generic to market the generic version of the patented drug.).

presumptively unlawful under the Sherman Act. The DOJ urged consideration of factors such as whether the settlement was greatly in excess of avoided litigation costs. It also stressed the need to weigh the consumer harm of the settlement stating that “if the settlement involves a payment in exchange for the generic manufacturer’s agreement to withdraw its challenge to the patent and to delay entry, there is no need to determine whether the patent would in fact have been held invalid in order to conclude that the settlement likely disadvantaged consumers.” This Article argues as discussed in section V that the settlement’s effect on the ability of third-party generic challengers to compete should also be given substantial weight, particularly since settlement parties make a deliberate choice to remove those barriers or leave them in place.

V. REVERSE PAYMENT SETTLEMENTS, COVENANTS NOT TO SUE AND THIRD-PARTY GENERICS; THE CASE METHOD’S MYOPIA AS TO THE LONG VIEW

The MMA allows subsequent ANDA filers to bring a declaratory judgment proceeding to challenge the patent’s validity or seek a determination that its generic drug does not infringe on the patent. The MMA’s declaratory judgment provisions were “designed to prevent patentees from ‘gaming’ the Hatch-Waxman Act” by opening a door to trigger the 180-day exclusivity period.

Some patent holders have prolonged or thwarted the declaratory judgment process by failing to sue first or subsequent ANDA filers for infringement on all relevant patents and by unilaterally providing a covenant not to sue as to infringement of the remaining patents. This may be done in an attempt to deprive the subsequent ANDA filer of subject matter jurisdiction for the declaratory judgment proceeding. To obtain jurisdiction for a declaratory judgment action concerning the parties’ rights and request for relief, “actual

135. Brief for the United States in Response to the Court’s Invitation, In re Ciprofloxacin Hydrochloride Antitrust Litig., Arkansas Carpenters Health and Welfare Fund v. Bayer, AG, No. 05-2851-cv at 10, 19 (2nd Cir. July 6, 2009). This case is a related appeal of the same case at issue in the Federal Circuit Cipro decision.
136. Id. at 26.
138. Teva Pharm. USA, Inc. v. Novartis Pharm. Corp., 482 F.3d 1330, 1342 & n. 7 (Fed. Cir. 2007).
139. Id. at 1343, 1345.
140. Id. at 1335.
controversy" between the parties is necessary. 141 Plaintiffs seeking a declaratory judgment bear the burden of proving actual controversy by a preponderance of the evidence. 142

Ritchie commented that “[a]t its core, civil procedure seeks to ensure that proper jurisdiction is established in order to afford parties fair access to courts without requiring parties to be hauled into court inappropriately.” 143 The question is whether covenants not to sue terminate the case or controversy between the patent holder and the ANDA filer, even if it means the generic applicant cannot obtain a substantive judicial hearing on its claim that the NBD’s patent is invalid or that its generic drug does not infringe.

In MedImmune, Inc. v. Genentech, Inc., the Supreme Court held in 2007 that whether a declaratory action presents a justiciable controversy under Article III of the Constitution must be determined by examining “all circumstances.” 144 MedImmune rejected the Federal Circuit’s more limited “reasonable apprehension of suit test,” under which some covenants not to sue were found to deprive a subsequent ANDA filer of subject matter jurisdiction. 145

In Teva Pharmaceuticals v. Novartis, the Federal Circuit applied the MedImmune “all circumstances” test to determine that patent holder Novartis’ decision to sue for infringement on only one of the five patents implicated by a first ANDA filer’s submission to the FDA indicated that there was an actual case or controversy between the parties necessary for declaratory judgment jurisdiction. 146 The Federal Circuit found that Novartis’ suit on one patent placed “into actual dispute the soundness of Teva’s ANDA [Teva’s certification under paragraph IV that its application did not infringe on Novartis’ patents or that those patents were invalid] and Teva’s ability to secure

141. Patel, supra note 44, at 1091 (citing 28 U.S.C. § 2201(a) (2006); U.S. CONST. Art. III (specifying that cases or controversies between the litigants are a necessary basis for judicial power).
143. Ritchie, supra note 4, at 125.
145. Id. at 133 n.11; C.f. Teva Pharm. USA v. Pfizer, Inc., 395 F.3d 1324 (Fed. Cir. 2005), reh’g en banc denied, 405 F.3d 990 (Fed. Cir. 2005), cert denied, 546 U.S. 958 (2005) (applying the reasonable apprehension of suit test to find no case or controversy existed for a HWA declaratory judgment action brought by subsequent ANDA filer where the patent holder failed to sue the subsequent ANDA for infringement of two patents implicated by the filing).
146. Teva Pharm. USA, Inc. v. Novartis Pharm. Corp., 482 F.3d 1330, 1341-42, 1345-46 (Fed. Cir. 2007).
approval of the ANDA.” In Teva, Novartis did not issue a covenant not to sue on the remaining patents, a factor that left Teva open to future litigation on the remaining patents relevant to its generic drug application. For subsequent ANDA filers, covenants not to sue may foreclose litigation necessary to a declaratory judgment determination.

Caraco v. Forest Labs is an important post-MedImmune case that applied the “all circumstances” test in evaluating whether covenants not to sue deprived a subsequent ANDA filer of subject matter jurisdiction to challenge the NBD holder’s patents. Forest sued Ivax, the first ANDA filer, on one of the two patents relevant to Forest’s drug, the ‘712 patent, which expired earlier than then ‘941 patent which also pertained to the drug. In litigation between Forest and Ivax the court found that the ‘712 patent Forest sued on was valid, infringed, and enforceable.

Caraco subsequently filed an ANDA application and Forest sued Caraco for infringement of the same patent it had previously litigated against Ivax. Forest also unilaterally granted Caraco a covenant not to sue on the remaining patent with the stated goal “to confirm” that there was no case or controversy between the parties regarding the ‘941 patent. Caraco brought a declaratory judgment action and sought to sue on both patents.

The Federal Circuit held that in the context of the Hatch-Waxman Act, Forest’s covenant not to sue did not eliminate the controversy between the parties. The Federal Circuit emphasized that the Hatch-Waxman Act gave Caraco an economic interest in determining whether both patents were infringed because only such a determination could trigger Ivax’s exclusivity period and open the door for Caraco’s entry prior to the expiration the ‘941 patent, which expired after the ‘712 patent that was the subject of the litigation with Caraco and Ivax. The Federal Circuit noted that despite the covenant not to sue, Forest refused to concede that the ‘941 patent was invalid or not infringed by Caraco’s ANDA. Emphasizing the
HWA’s goals, the Federal Circuit concluded that Forest’s actions resulted in injury-in-fact necessary for jurisdiction because they potentially excluded non-infringing generic drugs if Caraco is correct that its generic drug does not infringe Forest’s ‘941 patent.\(^{156}\)

The Federal Circuit also evaluated a covenant not to sue a subsequent ANDA filer in the *Janssen Pharmaceutica N.V. v. Apotex.*\(^{157}\) Janssen held three patents relevant to Apotex’s application, referred to as the ‘663 patent, the ‘425 patent and the ‘587 patent.\(^{158}\) In a separate litigation to which Apotex was not a party, the Federal Circuit found the ‘663 patent to be valid and infringed.\(^{159}\) After Apotex served Janssen with notice of its subsequent ANDA application, Janssen sued Apotex for infringement of the ‘663 patent, but not the ‘425 or ‘587 patent, and provided Apotex irrevocable covenants not to sue on the latter two patents.\(^{160}\)

During the course of Apotex’s attempt to seek a declaratory judgment against Janssen that its subsequent ANDA filing did not infringe on Janseen’s patents or that they were not valid, Apotex stipulated as to “infringement, validity, and enforceability of the ‘663 patent based on the Federal Circuit opinion.”\(^{161}\) The Federal Circuit held that Apotex’s stipulation as to the validity of the ‘663 patent ended the case or controversy between the parties because Apotex could not market the drug until the end of the term for the ‘663 patent which expired earlier than the other relevant patents.\(^{162}\)

Apotex alleged actual injury remained because it would face a 180-day delay in marketing its generic once the ‘663 patent expired because of the exclusivity granted to the first ANDA filer, Teva who had previously settled with Jannsen.\(^{163}\) The Federal Circuit attributed the 180-day delay Apotex would experience in marketing its generic drug to the features of the Hatch-Waxman Act that allow the first ANDA filer a six month exclusivity period, and held that such delay did not create a case or controversy between the parties.\(^{164}\)

*Janssen v. Apotex* ultimately turned on the subsequent ANDA

---

156. *Id.* at 1292.
158. *Id.*
159. *Id.* at 1358 (citing *Janssen Pharmaceutica N.V. v. Mylan Pharm. Inc.*, 456 F.3d 644, 671 (D.N.J. 2006), *aff’d,* 223 Fed. Appx. 999 (Fed. Cir. 2007)).
161. *Id.* at 1358.
162. *Id.*
163. *Id.* at 1359.
164. *Id.* at 1360.
filer’s stipulation as to the validity of one of the relevant patents and the generic drug’s infringement on that patent, precluding a declaratory judgment to the contrary. Plaintiffs unwilling to stipulate as to the validity or infringement of any of the challenged patents may nonetheless be faced with covenants not to sue which create delay while a district and then an appellate court weigh “all circumstances” to determine if a case or controversy remains.

In Dey, L.P. v. Sepracor, Inc., the court found subject matter jurisdiction for a subsequent ANDA’s declaratory judgment action noting the subsequent ANDA had not stipulated as to the validity or infringement of any of the patents that precluded determination of the subsequent ANDA filer’s request for declaratory judgment. Absent such a stipulation, the Delaware district court properly emphasized the MMA’s goal and the HWA’s policies to “balance the need for pharmaceutical innovation with the need for generic drug competition.” It also cited Caraco favorably for its recognition that the HWA and its MMA amendment were intended to foster “early resolution of patent disputes when subsequent Paragraph IV ANDA filers are blocked by a first generic applicant’s 180-day exclusivity period.”

In Teva v. Abbott, the Delaware District Court recognized that the execution of covenants not sue on some but not all patent claims deprived the court of jurisdiction to hear the patent holder’s declaratory judgment claims as to the validity of two of the patents at issue, but did not deprive the court of jurisdiction to hear the generic competitors’ antitrust claims. Under this test, jurisdiction will be preserved only if the generic competitor also files an antitrust claim. If the patent holder refuses to sue the ANDA filer and issues covenants not to sue, that ANDA filer would have to allege that such actions violated the antitrust laws to fall within the jurisdictional basis found in Teva v. Abbott.

The MedImmune “all circumstances” test has limited the effectiveness of covenants not to sue as a mechanism to block jurisdiction by subsequent ANDA filers in many declaratory judgment actions. It has not, however, ended the substantial delays caused by litigation over covenants not to sue. Courts since MedImmune continue to thread the needle between Caraco and

---

166. Id. at 362.
167. Id.
168. Id. at 365.
Janssen to determine whether the facts of the case and "all circumstances" merit a determination that subject matter jurisdiction remains despite a covenant not to sue. This determination creates substantial delays in obtaining a substantive hearing about the declaratory judgment motion if a district court and appellate court must both decide whether subject matter jurisdiction exists in light of a covenant not to sue on some but not all patents relevant to the subsequent generic filer’s application.

For first ANDA filers, Congress requires cooperation in the litigation to hasten determination of whether the generic drug application should be approved. In Teva v. Novartis, the Federal Circuit emphasized that “Congress explicitly required that in exchange for the 30-month stay [during which the FDA would not approve the first ANDA application], patentees were to ‘reasonably cooperate in expediting the action’ of determining whether the paragraph IV patents were invalid or not infringed.” For subsequent ANDA filers there is no such duty to reasonably cooperate to expedite a declaratory judgment action. While the MMA authorized subsequent ANDAs to seek a declaratory judgment as to the patent’s validity or their non-infringement, it did not likewise require the patent holder to cooperate in ensuring those cases could be expeditiously heard.

The Federal Circuit noted that the patent holder Novartis’ actions in suing the first ANDA filer, Teva, on only one of five relevant patent claims attempted to insulate Novartis “from any judicial determination of the metes and bounds of the scope of the claims of its four . . . method patents . . ., a determination that is central to the proper function of our patent system and is a central purpose of the Hatch-Waxman Act.” The reasoning of Teva v. Novartis that declined to let the patent holder stymie the first ANDA’s declaratory judgment action regarding its generic application applies with equal force to subsequent ANDA filers. For those subsequent filers, the patent holder’s tactics to undercut jurisdiction or stall a declaratory judgment proceeding flout the MMA’s purpose to allow subsequent generics to seek such a judgment to trigger the first ANDA’s timeclock and jumpstart competition.

170. Id.
171. Id. at 1343 (citing Teva Pharm. USA, Inc. v. Pfizer Inc., 405 F.3d 990, 992 (Fed. Cir. 2005), reh’g en banc denied, (Gajarsa, J., dissenting)).
Courts and the FTC should examine whether a patent holder intends to use covenants not to sue and similar tactics in an attempt to remove declaratory judgment jurisdiction for ANDA filers, despite the absence of factors that make the case more like Jannsen. Patent holders must be mindful that objectively baseless litigation may create a patent misuse or sham litigation claim, opening the door to antitrust liability. While exercise of the right to petition the government is ordinarily immune from antitrust liability under the Noerr-Pennington doctrine, U.S. courts have recognized that abuse of the litigation process to limit competition falls outside the umbrella of Noerr antitrust immunity.

“A patent owner may be subject to antitrust liability for the anticompetitive effects of bringing suit if the accused infringer proves that the suit was a mere sham to cover what is actually nothing more than an attempt to interfere directly with business relationships of a competitor.” To meet the sham litigation test, the suit must be “objectively baseless in the sense that no reasonable litigant could reasonably expect success on the merits.” If it is determined to be baseless, the “defendant must prove by clear and convincing evidence that a plaintiff's activities were not really efforts to vindicate its rights in court,” but conceal “an attempt to interfere directly with the business relationships of a competitor.”

Some may argue that covenants not to sue are designed to prevent litigation and thus cannot be classified as falling within the sham or abuse of litigation exception to the right to petition the government recognized in Noerr-Pennington. Yet, covenants not to sue are often deployed strategically to try to prevent subject matter jurisdiction to hear an ANDA filer’s declaratory judgment petition on the merits, and spawn litigation about jurisdiction that often takes a year or more to litigate as the district then the appellate court reviews the jurisdiction issue. While the jurisdictional effect of a covenant not

176. Prof'l Real Estate Investors, 508 U.S. at 60.
177. Teva Pharm. USA, 580 F. Supp. 2d at 361 (citing C.R. Bard, Inc. v. M3 Sys., Inc., 157 F.3d 1340, 1368-69 (Fed. Cir. 1998)).
178. Id. at 361 (citing Prof'l Real Estate Investors, 580 U.S. at 60-61).
to sue a subsequent ANDA filer is litigated, the first generic usually remains parked in a blocking position, no forfeiture event has occurred, a subsequent generic applicant's attempts to seek declaratory judgments is stalled, prices remain high, and competition is foreclosed. The result is the same as abusive litigation; to delay or deter competition, whether by starting litigation or by attempting to deprive the generic competitor of jurisdiction to have their case heard.

This Article recommends that Congress require patent holders to report covenants not to sue ANDA filers to the FTC so that the FTC can monitor and evaluate the use of this and similar litigation tactics in delaying generic competition. The FTC should monitor and issue a report on whether covenants not to sue are being used inappropriately to delay or forestall judgment of legitimate claims and limit competition from generic drugs.

The MMA requires that parties to reverse payment settlements report such a transaction to the FTC.179 This requirement has informed the public about the frequency, type, and character of reverse payment settlements.180 Reporting covenants not to sue ANDA filers will shed light on what is often the second phase of a reverse payment settlement; an attempt to prevent the forfeiture triggers from occurring that would start the first ANDA’s clock, opening the way for subsequent generic competitors. Prompt reporting to the FTC of the use of such covenants in ANDA applications will allow the Commission to conduct a longitudinal analysis to assess the use and anticompetitive effect of the first ANDA settlement and attempts to block declaratory judgment actions by subsequent filers.181 This information is currently obscured by the case-by-case approach of litigation.182 Courts should take into account the FTC’s reports on the use of such covenants and other techniques that block subsequent ANDA competition in weighing the parties’ representations that their settlement does not block or limit third-party competition.

It is critical that courts examine the effect of reverse settlement agreements on third-party generics which may not enter the market

180. Hemphill, An Aggregate Approach to Antitrust, supra note 106, at 633 ("Agencies have a decisive advantage in collecting and synthesizing aggregate information, given their expertise, access to confidential information about regulated firms, and freedom to examine issues over a long period of time, outside the litigation context.")
181. Id. at 671 (arguing the FTC should seek full details about each settlement and collect from each brand-name firm a detailed catalogue of its dealing with generic firms).
182. Id. (noting that courts have little capacity to collect aggregate data).
while the agreement between the patent holder and the first generic stalls the start of the 180-day exclusivity period. Although that delay is caused in part by interpretation of the Hatch-Waxman Act and its amendments, certain reverse settlement agreements erect or maintain barriers to third-party entry by forestalling the legal judgments or actions that would start the clock. Covenants not to sue and similar tactics often delay attempts to restart that clock. The parties’ representations about use of such covenants and similar delay tactics in declaratory judgment actions by ANDA filers should be weighed as a factor in determining whether a settlement is anticompetitive.

VI. PROPOSED LEGISLATION REGARDING REVERSE PAYMENT SETTLEMENTS; THE NEED TO REGULATE COVENANTS NOT TO SUE AND THEIR EFFECT ON SUBSEQUENT ANDA FilERS

As of December 2009, Congress is considering two bills that would limit reverse payment settlements. The Senate bill, S. 369, states that its purposes are to:

(1) enhance competition in the pharmaceutical market by stopping anticompetitive agreements between brand name and generic drug manufacturers that limit, delay, or otherwise prevent competition from generic drugs; and

(2) to support the purpose and intent of antitrust law by prohibiting anticompetitive practices in the pharmaceutical industry that harm consumers. 183

The Senate bill creates a presumption that a settlement agreement “resolving or settling, on a final or interim basis, a patent infringement claim in connection with the sale of a drug product” ANDA application has anticompetitive effects and is unlawful if: “(i) an ANDA filer receives anything of value; and (ii) the ANDA filer agrees to limit or forego research, development, manufacturing, marketing, or sales of the ANDA product for any period of time.” 184

It creates an exception to that presumption if “the parties to such agreement demonstrate by clear and convincing evidence that the procompetitive benefits of the agreement outweigh the anticompetitive effects of the agreement.” 185 The bill lists a variety of factors to be taken into account in making that assessment of the

183. S. 369, 111st Cong. § 2(b) (as reported by Senate, February 3, 2009).
184. S. 369 §§ 28(a)(1); 28 (a)(2)(A)(i)(ii). Note that the Senate bill applies only to settlements of patent infringement claims, not to cases challenging the patent’s validity.
agreement's benefits and anticompetitive effects including "the length of time remaining until the end of the life of the relevant patent, compared with the agreed upon entry date for the ANDA product," and "any other factor that the fact finder, in its discretion, deems relevant to its determination of competitive effects under this subsection." 186 S. 369 gives the FTC authority to enforce the bill against "the parties to any agreement resolving or settling, on a final or interim basis, a patent infringement claim, in connection with the sale of a drug product." 187

The House bill, H.R. 1706, prohibits agreements "resolving or settling a patent infringement claim in which... an ANDA received anything of value; and... agrees not to research, develop, manufacture, market or sell, for any period of time, the drug that is to be manufactured under the ANDA involved and is the subject of the patent infringement claim." 188 The House bill provides exceptions to the above for agreements where the value the ANDA receives is the right to market the drug before expiration of the patent or [removal of] any other statutory exclusivity that would prevent the drug's marketing. 189

The bills do not lay out the rationale for only regulating reverse payment settlement cases that concern infringement claims as opposed to patent validity claims. This Article recommends that the bills be amended to clarify that they apply even if patent infringement is only one of the allegations filed in the course of the parties' litigation. This is necessary to avoid the patent holder's strategic abandonment of its infringement claim prior to settlement so that the settlement is based only on the patent validity claim, and thus falls outside of the scope of the statute contemplated by Senate bill S. 369 or House bill H.R. 1706.

The bills focus on only patent validity claims might have the unintended effect but predictable consequence of patent holders refusing to sue for infringement, relying instead on the generic's incentives to file a claim challenging the patent's validity. In response the generic may assert that its drug does not infringe the patent and seek a declaratory judgment on non-infringement. It should be anticipated, however, that the parties to a reverse payment settlement will have an incentive to drop the infringement claim before their

186. S. 369 § 28(b)(1),(7).
interim or final settlement in order to avoid scrutiny under any law limited to patent infringement claims.

S. 369 provides certain exclusions from the bill’s limits on HWA pharmaceutical settlements “in which the consideration granted by the NDA holder to the ANDA filer as part of the resolution or settlement includes...[a] covenant not to sue on any claim that the ANDA product infringes a United States patent.”190 The House bill, H.R. 1706, provides that the first ANDA’s 180-day exclusivity period would be forfeited by a court dismissal of a declaratory judgment action as to the patent’s validity for lack of subject matter jurisdiction, with or without prejudice.191 It would also require forfeiture of that exclusivity period if the “applicant files with the FDA Secretary a covenant by the patent owner that the patent owner will not sue the applicant for infringement with respect to the patent.”192

Unbargained-for covenants not to sue that stymie attempts to have a declaratory judgment heard should be distinguished from those given in consideration for termination of litigation whose result is to allow the generic drug to be marketed. In Caraco the Federal Circuit recognized that “a covenant not to sue on a patent ensures that the covenant’s recipient will not be liable for an injunction for infringement of that patent.”193 In Teva v. Novartis the Federal Circuit cited the HWA’s legislative history that recognized where a generic applicant has challenged a patent by filing an ANDA, a case or controversy will arise, except “in the rare circumstance in which the patent owner and brand drug company have given the generic applicant a covenant not to sue, or otherwise formally acknowledge that the generic applicant’s drug does not infringe.”194 This legislative history addressed a covenant not to sue the first ANDA filer that would allow that filer to seek FDA approval to market the drug.

For subsequent ANDA filers, covenants not to sue may have the opposite effect. They erect legal barriers to subject matter jurisdiction to seek a declaratory judgment of the patent’s invalidity and/or the generic’s non-infringement. Covenants not to sue deter entry by subsequent ANDA filers who must litigate whether the covenant deprives them of subject matter jurisdiction for a declaratory

190. S. 369 § 28 (d)(3).
judgment, adding litigation cost and delay to subsequent ANDA challenges and competition.

This Article recommends that Congress require that in weighing the barriers to third-party competition created by a reverse payment settlement, the fact finder should consider whether the settlement contains a binding representation that the patent holder has not and will not attempt to deprive a subsequent ANDA filer of subject matter jurisdiction to obtain a declaratory judgment as to the patent’s validity or non-infringement of the generic drug. Without such a representation a court or fact finder may only speculate as to whether the patent holder might try to block a subsequent ANDA filer from its day in court in a declaratory judgment action. Requiring a representation that covenants not to sue and similar tactics will not be used in an attempt to deprive a subsequent ANDA filer of subject matter jurisdiction will allow a fuller assessment of the settlement’s barriers to entry for third-party generic competitors. Where a patent holder has already tried to block subsequent ANDA filers from obtaining declaratory judgments through procedural challenges to subject matter jurisdiction, the reviewing court should take such facts into account in weighing whether the settlement with the first ANDA filers is anticompetitive.

Congress should also provide that the FTC retains jurisdiction to bring a case against the patent holder or NBD in a reverse payment settlement who, following approval of that settlement, uses covenants not to sue and similar tactics to forestall jurisdiction for declaratory judgment actions by subsequent ANDA filers, unless that subsequent ANDA filer has stipulated as to the patent’s validity or infringement by the generic drug. The bill should provide that such use of covenants not to sue to deprive a subsequent ANDA of subject matter jurisdiction creates a rebuttable presumption that it is anticompetitive in light of their predictable and often intended result of producing substantial delay in the substantive consideration of the subsequent ANDA’s petition.

To remove incentives for such delay tactics, Congress should require that patent holders and NBD makers ‘reasonably cooperate in expediting the action’ of a first or subsequent paragraph IV ANDA filter’s request for declaratory judgment as to whether the patents were invalid or not infringed.195 Reviewing courts and the FTC should also be required to weigh whether the settlement is in the public interest, including an evaluation of whether the settlement

maintains or removes barriers or delays that effect third-party efforts to obtain FDA approval to market generic drugs.

As suggested in the preceding section, Congress should require that patent holders and NBD makers report to the FTC the use of covenants not to sue generic ANDA filers. This is necessary to monitor the extent to which suits, or the lack of suits against subsequent ANDA filers, and covenants not to sue are designed to forestall declaratory judgments or triggers to permitting generic entry. Congress should require the FTC to monitor trends in the use of covenants not to sue and similar delay tactics against ANDA filers, report its findings to Congress, and make recommendations on any steps taken or needed to curb anticompetitive use of such procedures.

VII. CONCLUSION

This reflection reviews the developments in pharmaceutical settlements with potential generic drug manufacturers to highlight the need for legislative reform in this area and judicial scrutiny of the use of covenants not to sue and similar devices. Courts and the FTC must weigh the full panoply of tactics that delay, defer or discourage generic drug entry. They must evaluate whether a reverse payment settlement erects or maintains barriers to third-party competition in determining whether that settlement is anticompetitive.

This article suggests amendments to the pending legislation to strengthen the FTC's ability to monitor, assess, and take action to curb those delay tactics. The FTC can play a valuable regulatory role in collecting information on covenants not to sue as it does now for reverse payment settlements. These efforts will empower consumers, Congress, the Commission and the courts in assessing the effect of settlement or delay tactics such as covenants not to sue.

This Article also stresses that the presumption of patent validity does not apply to infringement cases where the patent holder has the burden of making a prima facie case of infringement. Particularly where there is strong evidence of non-infringement, such presumptions do not track the patent's scope and must yield to analysis of the agreement's anticompetitive effects in violation of the antitrust laws and the FTC Act. Neither should the procedural presumption of patent validity that primarily allocates to the plaintiff the burden of proof of showing non-validity be converted into a device for antitrust liability.

I commend the many contributions to antitrust law made by the Santa Clara Computer and High Tech Law Journal since its founding
more than twenty-five years ago. During the past five years the CJTLJ has highlighted many issues in antitrust and unfair competition law — the tension between contract, intellectual property and antitrust law; the factors to use in determining the appropriate standard to analyze conduct challenged as an antitrust law violation, and; the role of intellectual property and antitrust law in competition and innovation. It is my hope that this body of work contributes to the ability of courts, regulators, legislators, scholars, the business and legal communities and the public to promote incentives for innovation, while protecting competition and consumers.