



OBSERVATIONS FROM HATCH WAXMAN LITIGATION

By Geoffrey Mason

**As presented at DRI's Intellectual Property Litigation Seminar
Chicago, Illinois, September 4-5, 2008**

Introduction

Congress enacted the Hatch-Waxman Act in 1984 to expedite generic entry into the market and restore innovator patent life. Although the Act accomplished its dual purposes, it simultaneously created a new litigation scheme with unique settlement issues. This paper provides an overview of the Hatch-Waxman Act, commentary on a typical Hatch-Waxman litigation, and an analysis of reverse payment settlement agreements.

I. Pharmaceutical Industry Overview

For every successful drug that ultimately leads to a Hatch-Waxman case, there are at least 5,000 new chemical compounds that fail at some point prior to Food and Drug Administration ("FDA") approval. These failures become exponentially more devastating to innovator firms the later they occur in the FDA regulatory process. Pharm. Research and Mfrs. of America, *Pharmaceutical Industry Profile 2007*, 5-6 (Mar. 2007) (hereinafter "Industry Profile 2007"), available at [www.phrma.org/files/Profile 2007.pdf](http://www.phrma.org/files/Profile%2007.pdf). Therefore, Hatch-Waxman cases deal only with the rare successes because only such successes attract generic imitation. Moreover, the low success rate of innovator drugs is critical to the generic business model because the price of innovative failure is borne entirely by the innovator drug firms. This central cost advantage permits generics to offer drugs at prices that innovator drug firms cannot match.

Although the below scheme is the typical path for a newly discovered drug to follow to market and then Hatch-Waxman litigation, it is not the typical path for thousands of new drugs discovered every year. In fact, it is an extraordinarily unlikely path that becomes more rare as drug-discovery costs continue to increase. For example, the cost of discovering a new drug in 1976 averaged \$54 million; in 2001, the cost had risen to \$802 million. *Industry Profile 2007* at 5. In sum, it is extremely rare for a new drug compound to progress from the lab bench to FDA approval and commercial launch. To the extent that these rare successes follow a common path, it is summarized below.



II. Hatch-Waxman Overview

Congress enacted the Hatch-Waxman Act in 1984. Since its introduction, Hatch-Waxman cases have become extremely popular with the pharmaceutical industry, ultimately playing a critical role in increasing the market presence of generic drugs. For example, generic drugs now comprise over 47% of the pharmaceutical market – up from 19% in 1984. FTC, Generic Drug Entry Prior to Patent Expiration 3 (2002) (herein after “FTC Study”), www.ftc.gov/os/2002/07/genericdrugstudy.pdf. Accordingly, Hatch-Waxman litigation is a critical part of most patent litigation practices.

To understand Hatch-Waxman practice, however, requires familiarity with both the FDA regulatory scheme and the statute itself.

A. The Creation of the Modern FDA

Today, the FDA approves all drugs for safety and effectiveness. 21 C.F.R. § 314.2 (2007). But the original Federal Food, Drug, and Cosmetic Act (“FFDC”) of 1938 only required the FDA to approve drugs for safety. In the years that followed, many in the pharmaceutical industry came to believe that an efficacy requirement should be added to the FDA’s review requirements. Despite such sentiments, however, legislative changes did not occur. This inactivity abruptly changed in 1961 when thalidomide, an inadequately tested drug, resulted in thousands of children being born with birth defects. This tragedy sparked a national outrage and prompted an immediate legislative response. As a result, Congress added a proof-of-efficacy requirement to new drug approval in the 1962 amendments to the FFDC.

B. The FDA Approval Process

The 1962 amendments implemented the proof-of-efficacy provisions by requiring *all* drug firms to complete extensive safety and efficacy clinical trials before introducing or delivering any new drug into interstate commerce. The new FDA approval process, which is the same fundamental process followed today, included four distinct stages and averaged six to eight years to complete. FDA and the Drug Development Process, Publication No. FS 02-5, Feb. 2002, *available at* www.fda.gov/opacom/factsheets/justthefacts/17drgdev.pdf.

1. Investigational New Drug Application



The process begins with an innovator submitting an Investigational New Drug Application (“IND”) to the FDA prior to any human testing of its newly discovered compound. 21 C.F.R. §§ 312.20 and 312.22 (2007). The IND contains a compilation of all known information about the compound and includes: (1) an introductory statement giving the name of the drug and all active ingredients, (2) a description of all of the laboratory and animal testing that has been conducted to ensure the drug is safe to administer to humans, and (3) a description of the overall plan for investigating the drug. 21 C.F.R. § 312.23 (2007). The IND is automatically allowed thirty days after the FDA receives it. 21 C.F.R. § 312.40 (2007). Once the IND is allowed, the applicant can begin human clinical trials.

2. Clinical Trials

The second stage of the FDA approval process requires the applicant to conduct three phases of clinical trials. 21 C.F.R. § 312.21. During Phase I, the drug is administered to twenty to eighty healthy volunteers (i.e., the volunteers do not suffer from the condition under study). 21 C.F.R. § 312.21(a). The purpose of these trials is to determine the metabolism and pharmacologic actions of the drug in humans, the side effects associated with increasing doses, and, if possible, early evidence of effectiveness. *Id.*

The pharmacokinetic and pharmacological information gathered during Phase I is used to design a controlled and scientifically valid dosing regimen for Phase II trials. *Id.* Unlike Phase I testing, during Phase II the drug is administered to, on average, 100-150 volunteers who suffer from the condition under study. 21 C.F.R. § 312.21(b) (2007). The purpose of Phase II testing is to determine the drug’s effectiveness (i.e., therapeutic properties) and adverse side effects. *Id.* If the drug is sufficiently effective at therapeutic doses without undue side effects, then the drug moves into Phase III testing. *Id.*

Phase III testing also assesses safety and efficacy, but it does so on a much larger scale and for a significantly longer time than a Phase II trial. *Id.* § 312.21(c). For example, Phase III testing frequently involves thousands of volunteers and spans multiple years. *Id.* In addition, bioavailability studies are conducted on healthy volunteers to determine the active ingredient’s absorption and excretion rates. Phase III also requires the applicant to determine the best practice for administering the drug as well as the process for large-scale manufacture and quality control. *Id.*



3. New Drug Application

After the applicant completes all three phases of clinical testing, it moves into the third stage of the FDA approval process. The third stage of the FDA approval process requires the applicant to submit the results from all clinical testing to the FDA in a New Drug Application (“NDA”). 21 C.F.R. § 314 (2007). The FDA reviews the NDA and must determine that (1) the drug is safe and effective for its intended use, (2) the proposed labeling is appropriate, and (3) the methods used to manufacture and store the drug preserve the drug’s integrity, strength, quality, and purity. 21 C.F.R. § 314.125 (2007). After review the FDA either grants approval of the NDA, states that the application is approvable with clarification of certain issues, or explains to the applicant why the NDA is not approved. 21 C.F.R. §§ 314.105, 314.110, 314.120 (2007).

4. Orange Book

If the NDA is approved, the applicant enters the final stage of FDA approval. During this stage the applicant must list all patents covering the drug or a method of using the drug in the Approved Drug Products with Therapeutic Equivalence Evaluations (“Orange Book”), and the applicant begins Phase IV testing. 21 U.S.C. § 355(b)(1)(G) (2006). The purpose of Phase IV testing is to determine any rare or long-term side effects over a larger population for a longer time period. Although the FDA can require Phase IV testing, most companies conduct post-marketing studies even in the absence of a regulatory requirement.

C. Impact of the FDA Approval Process on Drug Firms

Needless to say, the newly created FDA approval process became extremely long and costly. As a consequence, innovators and generics became concerned of its impact on the effective life of patents.

1. Impact on Innovator Drug Firms

a. Reduced Effective Patent Life

Prior to the 1962 amendments, a patent could include as many as fifteen years of post-launch market exclusivity. But the new clinical trials and lengthier FDA regulatory process significantly curtailed this post-launch exclusivity to the point where the drug enjoyed approximately half as much base compound patent protection while on the market. *See* Pharmaceutical Research and Manufacturers of America, *Delivering on the Promise of Pharmaceutical Innovation*, White Paper, submitted to FTC and the Dep’t of Justice (Apr. 22, 2002), at 7-10, available at www.ftc.gov/os/comments/intelpropertycomments/phrma020422.pdf.

Moreover, this reduced effective patent life also cuts gross sales because drug sales dramatically increase during the first few years of market life so the later years of patent exclusivity are considerably more valuable. Accordingly, the once-powerful monetary incentives for drug discovery significantly diminished as FDA approval times increased. By 1978, the government realized that patent term restoration was necessary to sustain industrial innovation.

b. *De Facto* Patent Term Extension

This patent term diminution, however, was slightly offset by the *de facto* patent term extension that resulted from the extensive clinical trials that generic drug firms had to complete after the patent expired. Specifically, the 1962 amendments required generic drug firms to duplicate the safety and efficacy testing of innovator drug firms. Furthermore, the Federal Circuit's decision in *Roche Products v. Bolar Pharmaceuticals*, 733 F.2d 858 (1984), which held that the experimental-use exception did not apply to clinical trials conducted for FDA approval, prevented generics from beginning the clinical trials until the innovator's patent expired. This meant that a generic firm had to wait for the patent to expire before beginning the FDA approval process in order to avoid patent infringement. Accordingly, the innovator drug firm received an additional period of market exclusivity after the patent expired that corresponded to the FDA's review time of the generic drug.

Despite this *de facto* patent term extension, innovator firms lobbied to Congress that their patent term extension should correspond to their FDA experience instead of the generic drug firm's FDA experience. In that way, an innovator suffering a particularly torturous FDA review could be assured to win back in patent term their just due, rather than simply hope that by dint of regulatory accident, the follow-on generics would suffer the same fate. Therefore, innovators argued that a rule tailored to the facts of each individual situation was necessary, rather than simply hoping that on average FDA regulatory burdens would fall equally on both generics and innovators.

2. Impact on Generic Drug Firms

Generic drug firms unsuccessfully opposed a patent term extension. However, generic drug firms successfully argued that, with a statutory extension in place, the *de facto* term extension needed to be removed. Otherwise, the combination of the statutory patent term extension and the *de facto* term extension would provide the drug industry with a market exclusivity period/patent term longer than any other industry. Therefore, generic drug firms argued that *Roche Products* needed to be legislatively reversed so that they could begin clinical trials



during the patented period. By providing this safe harbor, generic drug firms would be ready to launch the generic drug the moment the patent expired.

Generic drug firms also argued that it was unnecessary for them to duplicate an innovator drug firm's clinical trials if the two drugs were bioequivalent. In essence, a generic drug is bioequivalent if it delivers the same amount of active ingredient into the patient's bloodstream in the same amount of time as the innovator drug. There are limitations, however, to a bioequivalence model because even though the same amount of active ingredient is delivered, the overall efficacy of the drugs might be very different. Melissa Healy, *Generics: Just As Good?*, Los Angeles Times, Mar. 17, 2008, available at <http://articles.latimes.com/2008/mar/17/health/he-generic17>.

These limitations have long been redressed through the mechanism of Citizen Petitions filed with the FDA. A Citizen Petition allows innovator drug firms to raise specific safety and efficacy shortcomings of a generic drug. The general public can also file a Citizen Petition. Apart from the Citizen Petition, however, the general public has few formal procedures for addressing concerns about generic drugs.

D. The 1984 Hatch-Waxman Act

Congress attempted to give innovator and generic drug firms everything they were asking for in the Drug Price Competition and Patent Term Restoration Act in 1984. The Hatch-Waxman Act thus came into being and drastically changed the pharmaceutical industry.

1. Term Extension

In response to innovator loss of patent term, Congress enacted patent term extension provisions. These provisions are codified at 35 U.S.C. § 156 (2004). Basically, these provisions reward patentees with a patent term extension that is equal to half of the time spent in clinical trials plus the entire time the FDA took to review the results of the clinical trials and approve the drug for market entry. *Id.* The extension granted to offset regulatory review cannot exceed five years, 35 U.S.C. § 156(g)(6)(A), nor can the total market exclusivity period exceed fourteen years, 35 U.S.C. § 156(c)(3). Although the term extension restored most of the effective patent life that innovator drug firms lost during increased FDA review, it did not quite restore the sixteen- to seventeen-year period of market exclusivity that had been typical under the safety-only FDA regime with *de facto* term extension. See Dale H. Gieringer, *The Safety and Efficacy of New Drug*



Approval, 5 Cato Journal 177, No. 1 (Spring/Summer 1985), available at www.cato.org/pubs/journal/cj5n1/cj5n1-10.pdf.

2. Safe Harbor Provision

The Hatch-Waxman Act also included provisions that responded to generic complaints. As an initial matter, the Act eliminated *de facto* patent term extension by expressly reversing the Federal Circuit’s *Roche Products* decision. Specifically, 35 U.S.C. § 271(e) (2003) created a safe harbor provision that allowed generics to perform the experiments and clinical testing required for FDA approval prior to the patent’s expiration.

3. Bioequivalence

Congress also accepted the generic drug firms’ position that bioequivalence should suffice for FDA regulatory review. *See* 21 U.S.C. § 355(j)(2)(A)(iv). Therefore, the Act only required generic drug firms to demonstrate bioequivalence. Once the generic firm demonstrated bioequivalence, it could rely on the innovator drug firm’s extensive safety and efficacy clinical testing to submit an Abbreviated New Drug Application (“ANDA”) and receive FDA approval.

4. Exclusivity Periods

At the same time, Congress ensured that innovator drug firms received at least a minimum period of market exclusivity for each drug discovery. This minimum term acts as a *de minimis* patent term if all else fails. Specifically, Congress barred the FDA from receiving or approving ANDA applications for a certain period of time after innovator product approval. For example, the FDA was prohibited from approving an ANDA application on an innovator drug firm’s new molecular entity (i.e., a new drug) for five years. 21 C.F.R. § 314.108(b)(2) (2007). The Act also created a three-year active moiety exclusivity, *id.* at § 314.108(b)(4), a seven-year orphan drug exclusivity, *id.* at § 316.31 (2007), and a six-month pediatric exclusivity, 21 U.S.C. § 355a (2006).

5. Technical Infringement

Apart from the exclusivity provisions, however, these new provisions strongly encouraged generics to challenge patents in court. Evidently accepting the generic firms’ position that it would be unfair to require generic firms to run the risk of being held liable for any damages before mounting a patent challenge, Congress created a scheme whereby submitting an ANDA constituted an act of infringement. This new scheme allowed a generic drug firm to initiate a patent



challenge without investing large sums of money or even marketing a product. Moreover, the Act included powerful incentives to prompt innovator drug firms to respond and file suit even though there was no likelihood of damages. *See* 35 U.S.C. § 271(e)(2) (2003).

a. Thirty-Month Automatic Stay

The main incentive for the innovator to file suit against the ANDA applicant was a thirty-month automatic stay of the generic's ANDA application if a patent infringement suit is filed. Specifically, if the innovator files suit within forty-five days of receiving notice of the ANDA, the FDA cannot approve the generic's ANDA applications. Without this automatic stay, a generic could potentially launch its product without awaiting resolution of any ongoing patent litigation.

b. Paragraph IV Certification

Specifically, an ANDA applicant can now infringe by making a so-called paragraph iv certification, providing notice to the FDA and innovator of detailed reasons regarding why the generic believes that the patent is invalid or not infringed. 21 U.S.C. § 355(j)(2)(A)(vii). Congress included two incentives to prompt ANDA applicants to make a paragraph iv certification. The first incentive allowed an applicant making a paragraph iv certification to subtract one year from the new chemical entity exclusivity period. Thus, a ANDA applicant could make a paragraph iv certification on a new chemical entity four years after launch, rather than the usual five. 21 C.F.R. § 314.108(b)(2).

c. 180-Day Market Exclusivity

The second incentive rewards the first successful paragraph iv ANDA applicant with 180-days of market exclusivity. During this period, the first-filer's product is the only generic product on the market. 21 U.S.C. § 355(j)(5)(B)(iv). This 180-day period can easily yield profits that significantly exceed the entire investment in the generic's patent challenge. For example, Barr Laboratories made over \$311 million during its 180-day exclusivity period after successfully challenging Eli Lilly's Prozac patent portfolio. A. Maureen Rouhi, *Beyond Hatch-Waxman*, 80 Chem. & Eng. News 53, no. 38 (Sept. 2002), *available at* http://pubs.acs.org/cen/email/html/cen_coverstory_8038_8038biogenerics2.html. The market exclusivity begins to run when either a district court judgment renders the patent invalid or not infringed, or the generic drug firm first commercially markets the drug. Pub. L. No. 98-417, § 101, 98 Stat. 1585, 1589 (codified as amended at 21 U.S.C. § 355(j)(5)(B)(iv)).



E. Popularity of Hatch-Waxman Litigation

In sum, the Hatch-Waxman Act addressed the central issues raised by innovator and generic drug firms. The Act rewarded innovator drug firms with an additional period of patent exclusivity. The Act also expedited generic entry to the market by creating a safe harbor provision and adopting bioequivalence. To implement these provisions, Congress also included numerous incentives to encourage patent litigation. It is these powerful incentive provisions that have made Hatch-Waxman cases the phenomenon they are today.

1. Litigation Incentives for Generic Firms

With these upside incentives in place, and no need to be concerned about damages, Hatch-Waxman cases have become extraordinarily popular with generics. In fact, most drug firms assume that a Hatch-Waxman patent challenge will be brought against every commercially significant drug. Although some drugs are not challenged for one reason or another, those cases are more the exception than the rule.

2. Litigation Incentives for Innovator Firms

As discussed above, the thirty-month stay prompts an innovator drug firm to file a lawsuit after receiving a paragraph iv notice. Apart from this stay, however, innovator drug firms have little to gain, and everything to lose, in Hatch-Waxman litigation. For example, Eli Lilly's blockbuster drug Prozac was generating approximately \$2 billion per year (i.e., \$5.5 million per day) in revenue prior to Barr's filing a paragraph iv certification against the Prozac patent portfolio. *See* [Eli Lilly Gets Prozac Blues](http://www.money.cnn.com/2000/08/09/companies/lilly/), www.money.cnn.com/2000/08/09/companies/lilly/. After Barr Laboratories successfully challenged the Prozac patent portfolio, Eli Lilly's stock price dropped by more than 30% in a single day. *Id.*

Accordingly, Hatch-Waxman litigation is now a ubiquitous and extremely serious undertaking.

II. A Typical Hatch-Waxman Litigation

Although Hatch-Waxman litigation has many similarities to other high-profile life science patent cases, there are a few important differences.

A. Pre-litigation Investigation

The Hatch-Waxman Act rewards patentees with a patent term extension. But the extension period can only be applied to one patent in a portfolio, 35 U.S.C. § 156(c)(4), and the patentee must identify that patent within sixty days of drug approval, 37 C.F.R. § 1.720(f). Frequently, however, patentees only consult prosecution counsel when making this decision. Although prosecution counsel provides valuable insight, the lack of a full pre-litigation analysis often results in the selection of a patent that is vulnerable in litigation. Many patentees fail to get a pre-litigation analysis of the listed patents for an innovator drug because potential litigation of the patents is typically four years away. For example, 21 U.S.C. § 355(c)(3)(E)(ii) prevents a generic from filing a paragraph iv certification on a new chemical entity for four years. Despite this four-year gap, patentees should also consult litigation counsel and seek a pre-litigation analysis to determine the proper patent. In sum, a thorough and complete pre-litigation analysis prior to selecting the patent that will receive the extension is crucial.

B. Timeline

As discussed above, Hatch-Waxman litigation is initiated after one or more generics file an ANDA application with a paragraph iv certification. Within twenty days of the FDA's receipt of the ANDA application, the generic drug firm must notify the innovator drug firm of its application. 21 U.S.C. § 355(j)(2)(B)(ii)(I). Along with this notice, the generic drug firm must outline the basis for its belief that the patent is invalid or not infringed. *Id.* at § 355(j)(2)(B)(iv)(II). To the extent the generic alleges noninfringement, the generic is also required to make a confidential offer of access to its ANDA. *Id.* Within forty-five days of receiving the generic's notice, the innovator drug firm must file a patent infringement action if it wants the advantage of the thirty-month automatic stay. *Id.* at § 355(j)(5)(B)(iii). As previously mentioned, the complaint cannot request damages because the safe-harbor immunizes the generic conduct at issue; instead, an injunction is requested to prevent generic launch until after the patent(s) in suit expires. 35 U.S.C. § 271(e)(4). Furthermore, Hatch-Waxman cases are overwhelmingly tried to a bench because damages cannot be requested.

C. Filing the Complaint

1. Access to Generic's ANDA

Although forty-five days may seem a more than adequate time to file a Hatch-Waxman complaint, it does not take into account any discovery disputes between the parties or the complexity of the relevant patents. For example, the statute only requires that the generic offers access to the ANDA for the forty-five day clock to begin to run; it notably does not require actual disclosure of the



ANDA. 21 U.S.C. § 355(j)(2)(B)(iv). If the generic does not cooperate, then it is extremely difficult for the plaintiff to obtain the information it needs to determine whether the generic drug infringes the patent. Moreover, this dispute occurs before a case has been filed, so it cannot be readily resolved by motion practice or court orders. Despite these hurdles, the innovator must determine to file suit within forty-five days or it will lose the thirty-month stay.

2. Rule 11 of the Federal Rules of Civil Procedure

The usual difficulty in obtaining an ANDA is further compounded because the ANDA, even once disclosed, may not address the central Hatch-Waxman infringement issue: will this generic product, upon marketing, infringe the patents in suit? The ANDA may not address product characteristics that are irrelevant to safety and efficacy issues, as they are not required to be submitted by the FDA. However, those product characteristics may be extremely relevant to a patent infringement analysis. To the extent the claims of the patent turn on issues that the ANDA does not address, then discovery of samples of the product and the drug-development work leading up to the ANDA become critical. In fact, some innovators have undertaken years of experimental work to prove infringement.

While a full discussion of these issues and how they have been handled in a variety of different cases is well beyond the scope of this overview, suffice it to say that pre-suit investigations in Hatch-Waxman cases potentially take on a far greater level of urgency than in other types of patent infringement cases. As a result, innovator drug firms retain Hatch-Waxman litigation counsel as early as two years before ANDAs can be filed. This early and vigorous pre-litigation investigation and planning is critical to ensure that the forty-five day filing deadline is met and a thirty-month stay is obtained in a manner consistent with the limits of Rule 11 of the Federal Rules of Civil Procedure.

D. Litigation Aspects of the Thirty-Month Stay

1. Modification of the Stay

If the innovator drug firm files a complaint within forty-five days after receiving the generic's paragraph iv notice, then the FDA may not approve any ANDA applications until the earliest of (1) the patent expiring, (2) the district court entering judgment that the patent is invalid or not infringed, or (3) thirty-months passing. 21 U.S.C. § 355(j)(5)(B)(iii). The thirty-month stay gives the innovator drug firm the benefit of its patent during litigation. A district court, however, has the ability to modify the stay depending on the parties' conduct during litigation. *Id.* If the district court determines that the innovator drug firm



failed to “reasonably cooperate in expediting the action,” it will shorten the stay accordingly. *Id.*

In practice, this provision works as advertised. While innovators surely benefit economically from a longer litigation timetable, this incentive to delay is more than matched by the disincentives created by this provision. The loss or modification of a thirty-month stay is a devastating sanction. Recognizing that, innovators work extremely hard to stay clear of any such result.

2. At-Risk Launches

Occasionally, Hatch-Waxman cases exceed thirty months. When this happens, innovator drug firms are faced with the possibility of an at-risk launch by the generic because the FDA can approve ANDAs after the thirty months expire regardless of ongoing litigation. Once a generic receives FDA approval, it can legally market its drug. While generics in the past may have generally been averse to damages, today’s generics are extremely aggressive. Therefore, innovators should thoroughly investigate the past conduct of all generics regarding compliance with FDA regulations including past at-risk launches, current generic policies regarding at-risk launches, as well as the generic’s specific plans in this litigation. All of these areas should be thoroughly explored through contention interrogatories, Rule 30(b)(6) depositions, and supporting document requests.

Apart from these differences, Hatch-Waxman cases are very similar to other life-sciences patent litigations involving similar amounts in controversy. The Hatch-Waxman statute did not replace the patent system, but it created a few fairly dramatic changes outlined above. Despite these changes, however, Hatch-Waxman cases are still won and lost based on questions of validity, enforceability, and infringement of the patent(s) in suit and not due to the unique features of the Hatch-Waxman Act.

III. Antitrust Implications of Reverse Payment Settlement Agreements

Another issue unique to Hatch-Waxman cases is the antitrust scrutiny imposed on settlement agreements. For example, in the 1990s, litigants began entering into “reverse payment agreements,” where innovator firms made payments to the generics in return for delayed entry. Such agreements came under attack by the FTC and created an evolving body of law unique to Hatch-Waxman cases.

A. *Per se* Illegality



1. *In re Cardizem*

In the past, concerns over the antitrust scrutiny surrounding the settlement of a Hatch-Waxman case have made settlements difficult, if not impossible, in the event the parties could only agree to reverse payment agreements. In August 1998, a number of state attorneys general and private actors filed antitrust actions against Hoechst Marion Roussel (“HMR”) alleging such an agreement relating to HMR’s Cardizem CD violated Section 1 of the Sherman Act. The following year, the FTC started reviewing these reverse payment agreements. In June 2000, the district court agreed with the Cardizem CD plaintiffs, holding on summary judgment that HMR’s reverse payment agreement was *per se* illegal. *In re Cardizem CD Antitrust Litigation*, 105 F. Supp. 2d 682, 699 (E.D. Mich. 2000). Then, three years later, the Sixth Circuit affirmed. *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 915 (2003). Not surprisingly, no reverse payment agreements were entered into between generics and innovators during this period. Summary of Agreements Filed in FY 2007: A Report by the Bureau of Competition (hereinafter “Summary 2007”), www.ftc.gov/reports/mmact/MMAreport2006.pdf.

The landscape has changed dramatically, however, as a result of Eleventh and Second Circuit decisions that ultimately reject the *In re Cardizem* holding of *per se* illegality of reverse payments. Although the Supreme Court has declined to grant *certiorari* to resolve this conflict, Hatch-Waxman litigants are nevertheless voting with their feet: no less than *fourteen* reverse payment agreements were entered into, in each of the past two years. *Id.*

Moreover, in on-going reverse payment litigation brought by the FTC, even the once-emboldened FTC does not press a *per se* illegality argument. *FTC v. Cephalon*, No. 1:08-cv-00244, (D.D.C. filed Feb. 13, 2008). Although *In re Cardizem* initially prevented parties from entering reverse payment settlement agreements, subsequent cases have minimized *In re Cardizem*’s impact.

Under Section 1 of the Sherman Act “[e]very contract . . . in restraint of trade . . . among the several States . . . is hereby declared to be illegal.” While literally prohibiting *every* agreement in restraint of trade, the Supreme Court has long recognized that Congress intended to outlaw only “unreasonable” restraints. *See, e.g., State Oil Co. v. Khan*, 522 U.S. 3, 10 (1997). Most restraints are evaluated under a “rule of reason.” *Id.* Under this approach, “the finder of fact must decide whether the questioned practice imposes an unreasonable restraint on competition, taking into account a variety of factors, including specific information about the relevant business, its condition before and after the restraint was imposed, and the restraint’s history, nature, and effect.” *Id.* Other restraints,



however, “are deemed unlawful *per se*” because they “have such predictable and pernicious anticompetitive effect, and such limited potential for procompetitive benefit.” *Id.* “*Per se* treatment is appropriate ‘once experience with a particular kind of restraint enables the Court to predict with confidence that the rule of reason will condemn it.’” *Id.*

While acknowledging that framework, the Sixth Circuit in *In re Cardizem* held that the reverse payment agreement between HMR and Andrx “was, at its core, a horizontal agreement to eliminate competition in the market for Cardizem CD throughout the entire United States, a classic example of a *per se* illegal restraint of trade.” *In re Cardizem CD*, 332 F.3d at 908. The Sixth Circuit further held that “[n]one of the defendants’ attempts to avoid *per se* treatment is persuasive.” *Id.* The Sixth Circuit continued that, as “explained in greater detail in the district court’s opinion, the Agreement cannot be fairly characterized as merely an attempt to enforce patent rights *or an interim settlement of the patent litigation.*” *Id.* (emphasis added).

Given that this agreement was in fact entered into in order to settle a then-ongoing Hatch-Waxman patent litigation, this was a fairly startling assertion by the Sixth Circuit to make on review of the grant of summary judgment. The Sixth Circuit explained that “[a]s the plaintiffs point out, it is one thing to take advantage of a monopoly that naturally arises from a patent, but another thing altogether to *bolster the patent’s effectiveness* in inhibiting competitors by paying the only potential competitor \$40 million per year to stay off the market.” *Id.* (emphasis added). The Sixth Circuit then dropped a footnote immediately following the italicized phrase, noting that “when the Cardizem [district] court condemned the HMR/Andrx Agreement, it emphasized that the agreement [there] restrained Andrx from marketing other bioequivalent or generic versions of Cardizem that were not at issue in the pending litigation, Thus, the Sixth Circuit found that the agreement’s restrictions extended to noninfringing *and/or potentially noninfringing* versions of generic Cardizem.” *Id.* at 909 n.13. (emphasis added). In short, the fact that the agreement *might* have extended beyond the scope of HMR’s patent rights made it a *per se* violation of the Sherman Act. *Id.* at 909 n.14.

B. Exclusionary Effects of Patent Rights

1. *Valley Drug Co. v. Geneva Pharmaceuticals, Inc.*

Three months later, in an appeal from another reverse payment antitrust



action, the Eleventh Circuit politely disagreed. In *Valley Drug Co. v. Geneva Pharmaceuticals, Inc.*, the Eleventh Circuit reversed summary judgment that certain reverse payment settlement agreements were *per se* illegal, holding that each agreement at least appeared to be “no broader than the *potential exclusionary effect of the ‘207 patent.*” 344 F.3d 1294, 1305-06 (11th Cir. 2003) (emphasis added). Therefore, the court remanded the case for further consideration of the *actual* exclusionary effect of the ‘207 patent. *Id.* The Eleventh Circuit noted that “[w]e recognize that the Sixth Circuit appeared to take the opposite view . . . [in *in re Cardizem*].” *Id.* at 1310. “When the exclusionary power of a patent is implicated, however, the antitrust analysis cannot ignore the scope of the patent exclusion.” *Id.*

The Eleventh Circuit observed in a footnote that the Sixth Circuit’s decision “might reflect some reliance on the restriction on non-infringing products,” which would, of course, have involved consideration of the scope of patent exclusion. *Id.* at 1311 n.26. The Eleventh Circuit then rejected this, however, noting that the opinion “did not purport to measure the several provisions against the exclusionary power of the patent, or differentiate between provisions that fell within the scope of the patent’s protection and those which did not.” *Id.* Accordingly, the Eleventh Circuit reiterated its original disagreement: “[t]o the extent that the Sixth Circuit suggests that settlement of patent litigation was a *per se* violation of the antitrust laws merely because it involves a generic’s agreement to delay marketing until resolution of the patent infringement case in exchange for exit payments, we respectfully disagree.” *Id.* The Eleventh Circuit concluded by holding: “[w]e believe that the potential exclusionary power of the patent must first be considered.” *Id.*

2. *Schering-Plough Corp. v. FTC*

In the *interim* period prior to this welcome clarification of the application of the Sherman Act to reverse payment settlement agreements, the FTC had thoroughly warmed to the *Cardizem* approach. The FTC in fact filed, some two years prior to *Valley Drug*, an administrative action against Schering-Plough Corp. and others, alleging that their reverse settlement payments to certain generics *per se* violated Section 1 of the Sherman Act and Section 5 of the FTC Act. *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1061 (11th Cir. 2005). After a full trial, the ALJ found that the agreements were lawful, as indeed they would be under *Valley Drug*, and dismissed the complaint, noting that the FTC’s arguments to the contrary required a presumption that either the patents were invalid or not infringed. *Id.* at 1061-62. On appeal, the full Commission reversed, just as *Cardizem* would have permitted. *Id.* at 1062.



However, the Eleventh Circuit reversed the Commission, holding the agreements lawful and reiterating its holding in *Valley Drug* that the focus must remain on whether “the exclusionary effects of a reverse payment agreement fall within the scope of the patent’s protection.” *Id.* at 1076. The Eleventh Circuit relied heavily on the admission of the FTC that it couldn’t prove that the patent that was the subject of the settlement agreement was invalid or not infringed. *Id.*

While the FTC petitioned for a writ of *certiorari*, arguing that the Eleventh and Sixth Circuits were in conflict, the Supreme Court denied *certiorari*. *FTC v. Schering-Plough Corp.*, 402 F.3d 1056 (11th Cir. 2005), *cert. denied*, 74 U.S.L.W. 3722 (U.S. June 26, 2006) (No. 05-273). The Second Circuit followed suit in *In re Tamoxifen*. 429 F.3d 370 (2nd Cir. 2005). Specifically, the court held, just as the Eleventh Circuit had, that the lawfulness of a reverse payment settlement agreement is contingent on whether the exclusionary effects of the agreement fall within the patent’s protection. *Id.* at 397-401.

3. *FTC v. Cephalon*

Perhaps due to these developments, when the FTC filed suit against Cephalon four months ago claiming that certain generic reverse payment agreements were anticompetitive because the agreements cover products beyond the scope of the patent at issue, the FTC did not even allege *per se* illegality. *FTC v. Cephalon*, No. 1:08-cv-00244, (D.D.C. filed Feb. 13, 2008). Instead, the FTC alleged that the patent covers a particle size that could easily be circumvented by generics. *Id.* While Cephalon is ongoing today, and a motion to dismiss is pending at the time we go to press, it does appear that perhaps the *Cardizem* approach of merely analyzing *potential* rather than *actual* patent scope is outdated. Certainly, many litigants are behaving in that fashion.

Accordingly, while antitrust scrutiny of any Hatch-Waxman settlement agreement is still vitally important, the antitrust pall cast by *Cardizem* appears to be all but lost to history, facilitating reasonable settlement of Hatch-Waxman cases when circumstances permit.