

**HEALTH CARE AND INTELLECTUAL PROPERTY
COMMITTEE**

Section of Antitrust Law

**The Hatch-Waxman Act: Ground Zero In
The Interface Between Antitrust
And Intellectual Property**

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I. Introduction

- A. This outline is being provided in conjunction with the program entitled, "The Interface Between Antitrust and Intellectual Property: Lessons from the Healthcare Industry" (ABA Antitrust Section Spring Meeting, March 2001).
- B. After an overview of the Hatch-Waxman Amendments, we present a recent case study of how one NDA holder has reacted to the potential onset of generic competition and how the federal agencies (FDA and FTC) and the courts have responded thus far.
- C. We then discuss the issue of partial settlements as one means of furthering the goals of Hatch-Waxman.

II. Overview of Hatch-Waxman Act

- A. Congressional Intent
 - 1. Congress passed the "Hatch-Waxman Amendments," 21 U.S.C. § 355(j) and 35 U.S.C. § 271(e), after concluding that the Food Drug & Cosmetic Act's "cumbersome drug approval process delayed the entry of relatively inexpensive generic drugs into the marketplace." Mylan Pharmaceuticals, Inc. v. Shalala, 81 F.Supp.2d 30, 32 (D.D.C. 2000)
 - 2. The Hatch-Waxman Amendments are designed to promote the development of new drug products while still enabling competition and directly benefiting patients and other consumers by facilitating the introduction of less expensive, generic versions of brand name drugs. Mylan v. Shalala, supra.
 - 3. "Congress sought to get generic drugs into the hands of patients at reasonable prices – fast." In re Barr Labs, Inc., 930 F.2d 72, 76 (D.C. Cir. 1991).
- B. Mechanics of Hatch-Waxman
 - 1. ANDA

An innovator drug is approved by FDA based on a new drug application ("NDA"). Hatch-Waxman authorizes generic manufacturers to seek regulatory approval of a generic product based on an abbreviated new drug application ("ANDA"). The ANDA applicant may rely on the clinical testing data set forth in the NDA. The bioequivalency of the proposed generic product to the brand name version is assessed without the need for extensive additional clinical trials.

2. Patent Certifications

The ANDA applicant must certify (in one of four ways) that the generic does not infringe any patents that claim the brand name drug. Such patents are listed in FDA's official "Orange Book." For example, a Paragraph IV certification "permits the applicant to allege that the patent for the pioneer drug is either invalid or will not be infringed by the marketing of the generic drug." Mylan v. Shalala, *supra*, at 32.

- a) The NDA holder has 45 days from the date of receipt of Paragraph IV notice to file infringement action.

A Paragraph IV certification is considered to be an "artificial" act of infringement. Upon receiving notice of the filing of a Paragraph IV certification, the patent holder or pioneer manufacturer has 45 days in which to file suit against the generic manufacturer. One of the purposes of the regulatory structure and the "artificial" infringement act was to resolve competing claims in court quickly. Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 675-677 (1990). It is pro-competitive to hasten the conclusion of this type of litigation. See, e.g., In re '639 Patent Litigation, 1999 WL 528806, *1, n.1 (D. Mass.) ("The nature of ANDA litigation is particularly time sensitive").

- b) The generic manufacturer that files the ANDA may not file a declaratory judgment suit “with respect to the patent” for 45 days from and after the date of notification, raising a number of questions:

Is a “delisting action” – discussed below – by which a generic seeks to have the brand delist a patent from the Orange Book an action “with respect to the patent”? Ben Venue Laboratories, Inc. v. Novartis Pharmaceutical Corp., 10 F.Supp.2d 446 (D.N.J. 1998), says no.

Is a delisting action an action for a declaratory judgment? See Mylan Pharmaceuticals v. Thompson, No. 00-2876 (RMU) (D.D.C. March 13, 2001)

Can the 45-day rule be avoided by suing for delisting before giving notice? Cf. American Bioscience, Inc. v. FDA, No. 00-2247 (D.C. Cir.); Andrx Pharmaceuticals, Inc. v. Biovail Corporation International, No. 01-6194 (S.D. Fla)

- c) 30-Month Stay of Final FDA Approval of the ANDA

Once an action for patent infringement is brought, final FDA approval of the ANDA is held up for 30 months or until the litigation (which for most ANDAs these days includes appeal) is resolved in favor of the generic manufacturer, whichever comes first. If, however, the brand-name entity does not bring suit, then final approval can be granted without delay, assuming all other requirements have been met.

3. 180 Days of Exclusivity for “First Filer”

The Hatch-Waxman Act rewards the first ANDA filer or applicant “challenging” a patent holder by granting that applicant the right to be the sole authorized marketer

of the generic product (other than the brand) for a period of 180 days.

a) Triggers of Exclusivity Period

(i) Commercial Marketing

One of the two most common ways of triggering the 180-day exclusivity period is for the generic producer to begin marketing its drug commercially.

(ii) Court Decision

The other most common trigger is a court decision finding the pioneer drug maker's patent invalid or not infringed.

b) 3rd-Party Declaratory Judgment

Even after a generic manufacturer files the first ANDA, any company with an ANDA for a generic form of the same brand-name can seek a declaratory judgment of non-infringement or invalidity. Success on such a claim would commence the running of the first-filer's exclusivity period regardless of the status of the first-filer's litigation *or* its decision to refrain from marketing its own generic. Teva Pharmaceuticals, USA, Inc. v. U.S. Food and Drug Admin., 182 F.3d 1003, 1005 n.3 (D.C. Cir. 1999).

c) FDA Proposal For "Use It Or Lose It" Trigger

FDA has proposed a "use it or lose it" triggering period in which the first generic manufacturer to file a Paragraph IV certification would have 180 days in which to trigger the 180-day exclusivity period, i.e., obtain a final court decision or go to market. 64 Fed. Reg. at 42,878.

The “use it or lose it” period would begin after a second filer had received tentative approval and (a) after the 30-month stay had expired if the first filer is involved in patent litigation, (b) a preliminary injunction prohibiting marketing had expired, or (c) where applicable, the statutorily described exclusivity period for the listed drug had expired. In re 180-Day Generic Drug Exclusivity for Abbreviated New Drug Applications, FTC Comment (www.ftc.gov/be/v990016.htm).

d) Courts Rejected FDA’s Prior “Successful Defense” Regulation

Until rejected by Courts of Appeal, FDA regulations previously provided that exclusivity would not be granted unless an ANDA filer “successfully defended against” patent litigation before another applicant was ready to obtain FDA approval. See Mova Pharmaceuticals Corp. v. Shalala, 140 F.3d 1060, 1065 (D.C. Cir. 1998) (quoting rule then in effect); see Granutec Inc. v. Shalala, 1998 WL 153410, *5 (4th Cir. 1998). To “successfully defend” under the former FDA regulations, the ANDA applicant had to obtain, through a favorable decision on the merits, a “final judgment from which no appeal can be or has been taken.” Mylan v. Shalala, *supra*, at 33 (quoting rule then in effect); see Teva Pharmaceuticals USA, Inc. v. U.S. Food & Drug Admin., 1999 WL 1042743, *3 (D.D.C. 1999) (rejecting FDA’s refusal to recognize dismissal for lack of subject matter jurisdiction as a “court decision”).

III. Costs and Risks in Patent Infringement Actions Under Hatch-Waxman

A. Costs and Risks to Generic Manufacturer

1. Damages for Marketing an Infringing Product

Given the substantial risks of marketing an infringing product, an ANDA applicant may reasonably opt to refrain from marketing its product until the brand name manufacturer's patent claims are resolved.

As one of the sponsors of the Hatch-Waxman Act explained at the time the statute was enacted, "[t]he facts of life are that a generic drug manufacturer will await, as a practical matter, until the decision of a court on a patent challenge before that manufacturer markets a generic drug. That is the information they have given us as to their practice." 130 Cong. Rec. 24,427 (1984). See also, Proposed Rules: Abbreviated New Drug Applications, 54 Fed. Reg. 28,872, 28,894 (1989) ("It serves the public interest to permit a prudent ANDA . . . to stay off the market until the litigation is resolved, thereby minimizing potential damages."); Mylan v. Shalala, *supra*, at 40; Andrx v. Friedman, 83 F.Supp.2d 179 (D.D.C. 2000). Mova, *supra*, at 1072 (assuming that first ANDA applicant will not bring product to market "until the first applicant's lawsuit finishes (maybe years later)").

a) Damages Measured By Lost Profits To Brand Manufacturer (35 U.S.C. § 284)

If the product were subsequently found to be infringing, the applicant could be liable to the patent holder for damages measured not by the applicant's profits but rather by the patent holder's lost profits. The damages recoverable by a patent holder are assessed without regard to whether or not the infringing party profited by its infringement. Stickle v. Heublein, Inc., 716 F.2d 1550 (Fed. Cir. 1983).

b) Liability for Treble Damages for Patent Infringement (35 U.S.C. § 284)

2. Risk of Shareholder Suits

- a) Challenges to business judgment to bring product to market in face of patent infringement claim
- b) Challenges to business judgment not to market after substantial investment

3. Unknown Time to Resolve Patent Action

- a) Hurdles to prevailing on summary judgment in patent case (e.g., dueling experts)
- b) Likelihood of reversal in Federal Circuit

The Federal Circuit reverses, in whole or in part, 53 percent of all patent infringement decisions from district courts, including summary judgments, bench trials and jury verdicts. Cybor Corp. v. FAS Technologies, Inc., 138 F.3d 1448, 1476 (Fed. Cir. 1998).

B. Costs and Risks to Brand-Name Manufacturer

- a) Failure to meet standard for preliminary injunction barring marketing of allegedly infringing product (Fed.R.Civ.P.65), thus allowing generic to market infringing product.
- b) Generic goes to market and then found to infringe, but cannot afford to pay damages
 - (i) Lost Profits
 - (ii) Treble Damages
- c) Timing of litigation/Likelihood of reversal in Federal Circuit
- d) Long-term disincentive to innovation

IV. One Case Study – The Late Listing of New Patents to Achieve Multiple 30-month stays

- A. Biovail Corporation is the NDA holder for Tiazac, an extended-release diltiazem product prescribed for the treatment of angina and hypertension. Andrx Pharmaceuticals, Inc. has filed an ANDA with FDA for its generic version of Tiazac, which has been tentatively approved since September 2000.
- B. The issues involved include abuse of Listing Regulation – 21 CFR § 314.53(c)

Proper listing requires (a) that the patent being listed “claim” a formulation used by the brand-name product; and (b) that a legitimate and bona fide infringement claim could reasonably be asserted against the brand name product.

- C. Questions Whether NDA Holder Can Stack Consecutive 30-Months Stay Periods by Late Listing of Patents
 - 1. Where does the statute say it can?
- D. Question Concerning Role of FDA in Policing Listing Abuses

FDA has said that “[its] role in listing patents is *purely ministerial*, and the agency has reasonably interpreted the relevant patent listing provisions of the FDC Act to require interested parties to resolve any disputes concerning the validity of a patent listing between themselves in private litigation.” Mem. of Fed. Defts in Supp. of Mot. to Dismiss (in Andrx v. Biovail) at 10; accord id. at 14; accord Ben Venue, supra, at 456; Watson v. Henney, Civ. No. S 00-3516, Mem. Op. at 4 (D. Md. Jan. 18, 2001).

- E. Cases discussing listing or de-listing:

- 1. Ben Venue, supra:

The court upholds the right to sue for delisting but denies preliminary injunction seeking delisting, finding that it is “very likely” that the patent was properly listed.

2. Zenith v. Abbott, 1996 U.S. Dist. LEXIS 22567 (D.N.J. 1996):

The court upholds the right to sue for delisting and denies Zenith's motion for summary judgment, finding issues of fact as to whether the patents are properly listed.

3. Watson v. Henney ("Buspar"), supra:

In adjudicating challenge to listing of "method of use" patent, the court applied APA and granted summary judgment to FAA because it could rely on patentholder's assertions.

4. Abbott Laboratories v. Novopharm (Terazosin), 104 F.3d 1305 (Fed. Cir. 1997):

The Federal Circuit approved order requiring Abbott to delist, finding trial court was "properly concerned" that its judgment would have "little effect" without delisting.

5. American BioScience, Inc. v. Bristol-Myers Squibb, 2000 WL 1278348 (C.D. Cal. Sept. 27, 2000):

No private right of action to remedy an alleged failure of BMY to comply with its obligations under the FDCA. An action to enforce or to restrain violations thereof may only be brought by and in the name of the United States. 21 U.S.C. § 337(a). (involved listing, not delisting; on appeal to the Ninth Circuit).

6. Andrx Pharmaceuticals, Inc. v. Biovail Corporation International, supra:

The Southern District of Florida found no private right of action under the FDCA, but held that a District Court's authority to police alleged abuses would arise when the patent holder sued the generic manufacturer. At that point, the generic manufacturer could ask the Court to shorten or extend the 30 month stay "because either party to the action failed to reasonably cooperate

in expediting the action,” (quoting 21 U.S.C. § 355 (j)(5)(B)(iii)) or for a declaration that multiple 30 month periods are not authorized by the statute or were not contemplated by Congress.

7. Mylan v. Thompson, No. 00-2876 (RMU) (D.D.C. March 13, 2001):

The D.C. District Court ordered that the brand request FDA to remove a patent on buspirone from the Orange Book. The district court also ordered FDA to grant immediate approval of generic buspirone. On March 27, the Federal Circuit denied a stay pending appeal.

F. Chronology of Tiazac-related events

1. Late 1995 — Biovail Begins Marketing Tiazac
2. July 31, 1998 — FDA Permits Andrx to File ANDA for Tiazac

In letter granting Andrx the right to file its ANDA, FDA states that it “has further determined that it would not be in the public interest to have Tiazac shielded from direct generic competition”.

3. August 25, 1998 — Andrx Certifies to the First Tiazac Patent

Andrx notifies Biovail that Andrx’s generic product will not infringe Biovail’s ‘791 patent. Biovail sues Andrx for patent infringement, necessitating 30-month delay in FDA approval of Andrx’s ANDA.

4. March 6, 2000 — District Court Finds Andrx Does Not Infringe ‘791 Patent

Biovail appeals.

5. March 14, 2000 — Biovail sues FDA

Biovail files a lawsuit in Maryland against FDA, seeking to ensure that FDA would not approve Andrx's ANDA before the expiration of the 30-month statutory stay.

6. March 16, 2000 — Biovail files Citizen Petition

Biovail files Citizen Petition with FDA to require Andrx to perform additional tests.

7. April 2000 — Andrx Informed of Late-Term Amendment

Biovail submitted a late-term amendment to Tiazac labeling to provide for new method of administering: rather than direct ingestion of capsules, product is "sprinkled" on applesauce. As a result, FDA required Andrx to conduct new bioequivalence studies, which it did, and the results of which were confirmed acceptable.

8. September 29, 2000 — FDA Tentatively Approves Andrx ANDA

FDA notifies Andrx that but for 30-month stay imposed by pending patent litigation, ANDA would receive final approval.

9. December 19, 2000 — The '463 Patent Is Issued

10. January 8, 2001 Biovail's Certifies the '463 Patent for Listing for Tiazac in FDA Orange Book

Eugene Melnyk, Chairman of Biovail Corporation:
"The undersigned declares that Patent No. 6,162,463 ***covers a formulation*** of the drug diltiazem hydrochloride ***which is sold under the tradename Tiazac***. This product ***is currently approved*** under Section 505 of the Federal Food, Drug and Cosmetic Act."

11. January 30, 2001 — Biovail Announces Its Listing of the '463 Patent

12. February 1, 2001 — Andrx Notifies FDA of Its Objection to Biovail's Listing of the '463 Patent. Gives FDA until February 8, 2001.

Pursuant to its regulations (21 CFR § 314.53) and consistent with its numerous previous assertions that it has no patent expertise and that its function in this regard is "ministerial", FDA responds to Andrx's objection by simply asking Biovail to confirm the listing. Unless Biovail voluntarily withdraws the listing, FDA expects to take no further action.

13. February 2, 2001 — FDA Requires Andrx to Certify to the '463 Patent

14. February 9, 2001 — Andrx Files Suit in Southern District of Florida Against Biovail and FDA to Compel Biovail to Delist '463 Patent

Andrx seeks preliminary injunctive relief in an effort to obtain expedited resolution of the matter in light of the irreparable harm the listing imposes on Andrx and on consumers who will be denied access to a lower-priced generic version of Tiazac.

15. February 13, 2001 — Federal Circuit Decision in Andrx's Favor in Prior Tiazac Patent Litigation

Because Andrx's ANDA was already tentatively approved by FDA in September 2000, FDA acknowledges that "Andrx's ANDA would have been eligible for final approval on" this date. (Mem. of Fed. Defts in Supp. of Mot. to Dismiss at 7)

16. February 26, 2001 — Biovail Responds to Andrx's Motion for Preliminary Injunction

Biovail reveals for the first time that its listing of the '463 patent is based on a new product that it is manufacturing but is not yet approved by FDA or selling, not on the product approved by FDA and actually being sold under the name Tiazac. Biovail

clarifies that it does not claim that the '463 patent covers its existing product:

To avoid the argument that Biovail needs prior FDA approval for the change and thus the patent was not properly listable, Biovail asserts that the new formulation does not improve safety or efficacy.

17. FDA admits that it lacks expertise in this area.

"FDA's role in listing patents is purely ministerial; FDA has neither the expertise nor the resources to resolve complex patent coverage issues." (Mem. of Fed. Defts in Supp. of Mot. to Dismiss at 15) (citing 54 Fed. Reg. 28,872, 28,909-10 (July 10, 1989)).

18. Does Biovail's proposed new product require prior FDA approval?

See, for example, the November 1999, FDA issued *Guidance for Industry: Changes to an Approved NDA or ANDA*, which provides:

"Changes in the qualitative or quantitative formulation, including inactive ingredients, as provided in the approved application, are considered major changes and should be filed in a prior approval supplement, unless exempted by regulation or guidance ([21 U.S.C. §] 506A(c)(2)(A))." (at 7)

"Major Changes (Prior Approval Supplement). The following are examples of changes that are considered to have a substantial potential to have an adverse effect on the identity, strength, quality, purity, or potency of a product as they may relate to the safety or effectiveness of the product.

1. ***Changes that may affect the controlled (or modified) release***, metering or other characteristics (e.g., particle size) of the dose delivered to the patient, including the addition or deletion of a code imprint by embossing, debossing, or engraving on a modified-release solid oral dosage form" (at 12)

19. February 28, 2001 — Federal Defendants' (FDA's) Notice of Change in Position

Upon reviewing Biovail's opposition to Andrx's motion, FDA tells Court that the '463 patent should not be listed:

In its original Certification and its response to FDA's request for confirmation, "Biovail *appeared to indicate* that the '463 patent claimed the approved drug product Tiazac". (Fed. Defts' Notice of Change in Position at 2)

"*Contrary to Biovail's assertions*, FDA believes that the changes in formulation and manufacturing of Tiazac described by Biovail are not in fact covered by the approved NDA for Tiazac." (Id. at 3)

"[W]here an NDA holder in a lawsuit makes subsequent representations that show on their face that the patent which allegedly claims the approved drug product at issue actually claims a different, unapproved, formulation of the product, then it is proper and necessary for the agency to reconsider the listing of the patent". (Id. at 3-4)

"[I]t now appears from Biovail's newly submitted declarations that the '463 patent does not claim the drug product as originally approved, but only claims the product in its revised (and unapproved) form. ***Thus, by virtue of Biovail's own statements, FDA is now of the view that the '463 patent does not claim the approved drug product as required by the statute and therefore cannot be listed in the Orange Book for Tiazac.***" (Id. at 3)

20. March 1, 2001 — FDA Explanation of Position during Hearing

At the hearing on Andrx's motion for preliminary injunction, DOJ attorney explains that in light of the submissions by Biovail, FDA was "prepared unilaterally

to delist the patent". The reason it hadn't already done so, he said, was because the matter was before the court.

In response, Judge Dimitrouleas asked, "Why should I do the dirty work?" Transcript of March 1, 2001, Hearing before Judge Dimitrouleas.

21. March 1, 2001 — Biovail Refusal to Argue that Presently Approved Product is Covered by Patent
22. March 6, 2001 — District Court Denies Andrx Motion for Preliminary Injunction

Court holds that even if Biovail's listing of patent was fraudulent, Andrx has no private right to compel delisting under the FDCA prior to end of 45-day period, and that "[i]t is FDA's job to determine whether to list or delist a patent" (March 6, 2001 Omnibus Order at 9).

Court holds open possibility of remedy after 45 days runs and Andrx is sued for infringement; willingness to consider issue of multiple stays; to consider reducing the 30 month period

23. As of this writing, Biovail has not delisted
24. As of this writing, FDA has not delisted

V. Potential Theories of Liability for Multiple Listings (Assuming the Statute Permits Them)

A. Non-antitrust theories

1. Claim under FDCA: Is there a private right of action?
2. Claim under Patent Act
3. Constitutional limitations (i.e., Takings Clause)?
4. All Writs Act
5. State law

- a) Negligence *per se*
- b) Unfair Competition – common law or statutory bases
- c) Interference with prospective economic relations

But cf. Buckman Co. v. Plaintiff's Legal Committee, 121 S. Ct. 1012 (2001) (state-law fraud-on-the-FDA claims against manufacturer of medical device pre-empted by FDCA)

B. Federal Antitrust Laws (Sherman Act §§ 1, 2)

1. Fraud and analogy to Walker Process -- Fraud on FDA to secure exclusivity/delay under Hatch-Waxman
 - a) Analogy to Bad Faith Enforcement of a patent; Nobelpharma AB v. Implant Innovations, Inc., 141 F.3d 1059 (Fed. Cir. 1998); cf. Handgards, Inc. v. Ethicon, Inc., 601 F.2d 986 (9th Cir. 1979)
 - b) Analogy to patent misuse (amassing patents)
2. Essential facility doctrine -- Otter Tail Power Co. v. U.S., 410 U.S. 366 (1973)
 - a) The patent as the “essential facility”
 - b) Hatch-Waxman stays as the “essential facility”
3. Boycott; Refusal to Deal -- Placing entirely in the hands of a potential competitor whether competition occurs -- Lorain Journal Co. V. U.S., 342 U.S. 366 (1951); Aspens Skiing Co. v. Aspen Highlands Skiing Corp., 472 U.S. 585 (1985)
4. Intent-based claims -- U.S. v. Singer Mfg. Co., 374 U.S. 174 (1963)

VI. Can the Hatch-Waxman Abuses and Other Problems be Managed Through Interim Settlements?

A. Hypothetical Interim Settlement

1. Generic agrees not to market during pendency of patent infringement action.
2. In exchange, brand agrees to make “interim” payments to generic.

B. Examples of Partial Settlement Transactions Subject to Government Analysis

1. In re Abbott Laboratories and Geneva Pharmaceuticals, Inc., FTC Dkt. Nos. C-3945 and C-3946 (March 16, 2000); Litigation: In re Terazosin Hydrochloride Antitrust Litigation, 99-MDL-1317 (S.D. Fla.)
2. Aventis (Hoechst Marion Roussel, Inc.) and Andrx Corp., FTC Dkt. No. C-9293 (March 16, 2000); Litigation: In re Cardizem CD Antitrust Litigation, 98-MD-1278 (E.D. Mich.).

C. Antitrust Analysis Applied to Interim Settlements

1. Is there a cognizable restraint in the first place?
 - a) Is there a right to sell an infringing product?
 - b) Is an infringer an actual or potential horizontal competitor?
 - c) Does it matter if patients and consumers were benefitted?
2. Questions Whether Noerr-Pennington Immunity Applies

A party's conduct in connection with litigation is constitutionally immune from antitrust liability under the “Noerr-Pennington” doctrine. Eastern Railroad Presidents Conference v. Noerr Motor Freight, Inc., 365 U.S. 127 (1961); California Motor Transport Co. v. Trucking Unlimited, 404 U.S. 508 (1972); Ass'n of

Retail Travel Agents, Ltd. v. Air Transport Ass'n of America, 1985 WL 1635 (D.D.C. 1985).

Noerr-Pennington immunity for litigation-related conduct is intentionally broad and encompasses all formal and informal conduct — including settlement agreements — when, as a practical matter, the challenged conduct is inseparable from and attendant upon the litigation. Settlement decisions, pre-litigation threats, and litigation-related publicity have all been held to fall squarely within the class of immune conduct, even when such conduct transpires solely among the litigants without petition to or oversight by any court.

See, Hise v. Philip Morris Inc., 46 F. Supp.2d 1201 (N.D. Okla. 1999) (Noerr-Pennington immunity shielded tobacco companies' conduct arising out of settlement agreement with states' attorneys general); Columbia Pictures Industries, Inc. v. Professional Real Estate Investors, Inc., 944 F.2d 1525, 1528 (9th Cir. 1991), aff'd, 508 U.S. 49 (1993) (decision to accept or reject settlement offer is not separate and distinct from prosecution of suit, which is presumptively immune from antitrust liability); McGuire Oil Co. v. Mapco, Inc., 958 F.2d 1552, 1560 n.11 (11th Cir. 1992) (threats of litigation immune); Aircapital Cablevision, Inc. v. Starlink Communications Group, 634 F.Supp. 316, 326 (D. Kan. 1986) (publicity concerning lawsuit immune if underlying action is immune).

3. Questions Whether Rule of Reason or *Per se* Analysis Applies (Though Some Courts Simply Find The Practices Lawful)
 - a) Under the rule of reason, “the test of legality is 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.” Federal Trade Commission v. Indiana Federation of Dentists, 476 U.S. 447, 458 (1986) (quoting

Chicago Board of Trade v. United States, 246 U.S. 231, 238)

- b) A rule of *per se* illegality is appropriate in the antitrust arena when the conduct of the party is “manifestly anticompetitive.” Continental T.V., Inc. v. GTE Sylvania Inc., 433 U.S. 36, 49-50 (1977).

Recognizing that “considerable inquiry into market conditions” may be required before the application of any so-called *per se* condemnation is justified, the Supreme Court in its most recent ruling on the subject cautioned that condemnation of a business practice based on a truncated analysis may occur only in those very narrow circumstances in which “an observer with even a rudimentary understanding of economics could conclude that the arrangements in question would have an anticompetitive effect on customers and markets.” California Dental Association v. FTC, 526 U.S. 756, 770 (1999).

“A court should find a *per se* antitrust violation only when prior cases have established the anti-competitive effects of a sufficiently similar business practice.” Betkerur v Aultman Hospital Association, 78 F.3d 1079, 1089 (6th Cir. 1996) “Courts must be careful not to extend the *per se* treatment to a type of restraint literally falling within a *per se* category where the rationale of the generalization is not applicable.” United States v. Realty Multilist Inc., 629 F.2d 1351, 1365 (5th Cir. 1980).

Before an agreement can be classified under the *per se* mode of analysis, the courts must have sufficient experience to know that the agreement is a “naked restraint of trade with no purpose except stifling of competition” and that the agreement would have a “pernicious effect on

competition and lack any redeeming virtue.”
Northern Pacific Railway v. United States, 356
U.S. 1, 5 (1958); White Motor Co. v. United
States, 372 U.S. 253, 263 (1963).

4. Authorities Addressing Antitrust Analysis In Intellectual Property Context

- a) In intellectual property context, traditionally anticompetitive activity is authorized to enhance competition

The possession of intellectual property rights permits parties to engage in numerous forms of behavior that might otherwise violate the antitrust laws. For example, the holder of patent is expressly allowed to restrict the territory in which a licensee may practice the patent. 35 U.S.C. § 261. The exercise of that right cannot give rise to liability under the antitrust laws. Dunlap Co. v. Kelsey-Hayes Co., 484 F.2d 407, 417-18 (6th Cir. 1973).

In evaluating antitrust claims that relate to the exercise of patent rights, courts must be careful to separate and exclude from their analysis the lawful effect of the patent itself. Miller Insituform Inc. v. Insituform of America, Inc., 830 F.2d 606, 609 (6th Cir. 1987).

“... some agreements that would be unlawful if undertaken in the absence of a reasonable dispute may be lawful when used to settle a bona fide [intellectual property] dispute.” Herbert Hovenkamp, Antitrust Law (1998 & 1999 Supp.) ¶ 2046 at 265. (Formerly authored by Areeda & Turner)

- b) The intellectual property context generally demands a rule of reason analysis

Because agreements settling intellectual property disputes raise fundamentally different competitive concerns than other agreements between competitors, a mechanical (*per se*) application by analogy of the antitrust laws to settlement of patent disputes is inappropriate. See Standard Oil, Co. (Indiana) v. United States, 283 U.S. 163 (1931).

The different perspective on competition arising from agreements involving intellectual property demands a different analysis of the antitrust implications of such agreements. See e.g., Areeda, Turner, Hovenkamp, Solow and Elhaug Antitrust Law, multi-volume treatise Volume XII.

Courts evaluating restraints involving intellectual property rights consistently evaluate those restraints under the rule of reason, after considering the actual affects of the restraints on competition. E.g., B. Braun Medical, Inc. v Abbott Laboratories, Inc., 124 F.3d 1419, 1428 n.4 (Fed. Cir. 1997) (“By virtue of its patent rights ..., Braun has the right to exclude competition in each of these markets. Therefore the restricted sale does not constitute an altogether illegal horizontal restraint.”); E.I. du Pont de Nemors v. Berkley & Co., 620 F.2d 1247, 174 (8th Cir. 1980) (only where “patent is invalid as improperly issued and the patentee has illegally received exclusionary rights he would not otherwise have” is there any basis for antitrust violation); see also United States v. Westinghouse Electric Corp., 648 F.2d 642, 649 (9th Cir. 1981) (“the desire of Mitsubishi to avoid infringing upon Westinghouse’s many patents – perhaps even as to products only arguably covered by Westinghouse’s patents – undoubtedly has an effect on competition, but this is an effect which results from the monopoly granted by the patent

laws and does not establish an antitrust violation by the companies in this case").

- c) Settlements (Practices) which are claimed to extend patentee's statutory rights ordinarily analyzed under rule of reason – when analyzed at all (and not simply found to be lawful)

Virginia Panel Corporation v. Mac Panel Co., 133 F.3d 860 (Fed. Cir. 1997)

Mallinckrodt, Inc. v. Medipart, Inc., 976 F.2d 700, 708, 24 USPQ2d 1173, 1179-80 (Fed. Cir. 1992).

Zeneca Limited v. Pharmachemie, B.V., 37 F.Supp.2d 85 (D.Mass. 1999)

But cf. Aventis-Andrx, supra; Abbott-Geneva, supra.

- 5. Mechanical application of the antitrust laws to the intellectual property context is inappropriate

A patent grants a monopoly immune from antitrust law. E. Bement & Sons v. National Arrow Co., 186 U.S. 70, 91 (1902); see also, Continental Paper Bag Co. v. Eastern Paper Bag Co., 210 U.S. 405, 424 (1908) (patent confers a monopoly that the courts should respect); United States v Dubilier Condenser Corp., 289 U.S. 178, 186 (1933) (not proper to call rights granted to patent holder a monopoly because “a monopoly takes something from the people [but] an inventor deprives the public from nothing which it enjoyed before its discovery”).

“No court has ever held that the antitrust laws require a patent holder to forfeit the exclusionary power inherent in his patent the instant his patent monopoly affords him monopoly power.” SCM Corp. v. Xerox Corp., 645 F.2d 1195, 1204 (2d Cir. 1981), cert. denied 455 U.S. 1016 (1982).

6. Comments About Interim Settlements by FTC Commissioners
- a) Remarks of FTC Chairman Robert Pitofsky before the American Antitrust Institute Conference: An Agenda for Antitrust in the 21st Century, Washington, D.C., June 15, 2000.
 - b) Remarks of FTC Chairman Robert Pitofsky before the Antitrust, Technology and Intellectual Property conference, University of California, Berkeley, March 2, 2001.
 - c) Remarks of FTC Commissioner Sheila F. Anthony before the ABA "Antitrust and Intellectual Property: The Crossroads" Program, San Francisco, California, June 1, 2000.
 - d) Remarks of FTC Commissioner Thomas B. Leary, "Antitrust Issues in Settlement of Pharmaceutical Patent Disputes," before the Sixth Annual Health Care Antitrust Forum, Northwestern University School of Law, Chicago, November 3, 2000.