NJIPLA

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NEW JERSEY INTELLECTUAL PROPERTY LAW ASSOCIATION

PATENT LITIGATION SEMINAR

MARCH 13, 2013

The Woodbridge Hilton

Agenda – Session 1

Introduction

- Robert Rudnick – President NJIPLA (Gibbons, P.C.)

Opening Remarks by the Chair

- Immac J. (“Casey”) Thampoe – NJIPLA Chair (Merck & Co., Inc.)

Keynote Address: “***The Federal Circuit v. The Supreme Court”***

- Hon. Arthur J. Gajarsa (Wilmer, Cutler, Pickering, Hale, and Dorr, LLP)

“The Divided Court on Divided Infringement: What Comes Next?”

- Daryl L. Joseffer (King and Spalding, LLP)

“Willful Infringement: The Federal Circuit is Listening”

- Laura P. Masurovsky (Finnegan, Henderson, Farabow, Garrett & Dunner, LLP)

**********Break**********

Keynote Address

"*The Federal Circuit v. The Supreme Court*"

Honorable Arthur J. Gajarsa

(Wilmer, Cutler, Pickering, Hale, and Dorr, LLP)

The Divided Court on Divided Infringement: What Comes Next?

Daryl Joseffer
King & Spalding LLP
1700 Pennsylvania Ave., NW
Washington, DC 22007

The Issue

- If two or more entities combine to perform a patented method, are one or more of them liable for direct infringement?
- Can anyone be held liable for induced infringement?

The Issue

- For product claims, the entity that completes a patented product is liable for individually making the product.
- Any entity that puts a product into use may be liable for individually using the product.

Legal Background

- Until 2007, there was surprisingly little law on this issue.
- Not any more.

Legal Background

- In *BMC Resources*, the Federal Circuit held that an entity is liable for direct infringement only if it performs some steps and directs or controls the performance of the other steps.
- *BMC* also held that, if no one entity is liable for direct infringement, no one can be held liable for induced infringement, either.

The “Direction or Control” Test

- Subsequent cases held that “direction or control” means that the two direct actors had a principal-agent relationship.
- Even joint enterprise insufficient (*Golden Hour*).

The *En Banc* Decisions (*Akamai* and *McKesson)*

- None of the 11 members of the *en banc* court fully endorsed the recent panel decisions.

The *En Banc* Decisions (*Akamai* and *McKesson*)

- Direct Infringement
  - Majority passed
  - Judge Newman would blow it wide open
  - Other four dissenters would overrule *Golden Hour* to recognize “joint enterprise” liability

The *En Banc* Decisions (*Akamai* and *McKesson)*

- Inducement
  - The majority held that a party can be liable for induced infringement if it induces the combined performance of a patented method, whether or not one or more of the direct actors would be liable for direct infringement.
  - The majority remanded the *Akamai* and *McKesson* cases for further consideration under its inducement standard.

The *En Banc* Decisions (*Akamai* and *McKesson)*

- Inducement
  - Five dissenters called the theory radical because direct infringement is a predicate to indirect infringement.

Inducement

- Induced infringement has strict requirements
  - All method steps must be performed (though not by the same person)
  - Defendant must have specific intent to induce infringement
    - Knowledge of patent
    - Intent to cause the acts that constitute infringement

The *En Banc* Middle Ground

- For patentees, inducement is a limited remedy.
- For alleged infringers, summary judgment will be harder to come by than under *BMC.*

Is The Federal Circuit Done?

- The court could grant *en banc* again on direct infringement.
- No member of the *en banc* court endorsed the *BMC* line of decisions.

Practical Consequences
Claim Drafting

- It is best to draft claims by reference to only one actor.
- Applicants may consider drafting the same fundamental claim in different ways, to cover different direct actors or different ways that actors might combine to practice a method.
- Healthcare companies must navigate between this jurisprudence and Section 101.

Practical Consequences
Direct Infringement

- Defendants should generally be able to get summary judgment on direct infringement claims.

Practical Consequences
Indirect Infringement

- As a matter of law, the inducement remedy should not trap unwitting actors because of its high knowledge requirements.
- Defendants' knowledge may present a question of fact for trial.

FINNEGAN

Finnegan, Henderson, Farabow, Garrett & Dunner, LLP

Willful Infringement: The Federal Circuit is Listening

NPLA Patent Litigation Seminar

Laura Masurovsky

March 13, 2013

Overview – Willful Infringement

- Duty of Due Care – *Underwater Devices* (Fed. Cir. 1983)
- Demise of the Adverse Inference – *Knorr-Bremse* (Fed. Cir. 2004) (*en banc*)
- Willfulness Bar Is Raised – *Seagate* (Fed. Cir. 2007) (*en banc*)
- Willfulness Bar is Further Raised – *Bard* (Fed. Cir. 2012)

Willful Infringement

- Willful infringement entitles the patent owner to enhanced damages

Consequences Can be Severe

- A court may treble the damages awarded—35 U.S.C. § 284
- Fees for exceptional cases—35 U.S.C. § 285

Willful Infringement Damages

- Enhancing damages for willful infringement is a two-step process
  - Clear and convincing evidence that the infringing conduct rises to the level of "willful infringement"
  - Considering the totality of circumstances and determining whether damages should be enhanced

Pre-*Seagate* Standard for Willful Infringement

- *Underwater Devices, Inc. v. Morrison-Knudsen Co.*, 717 F.2d 1380 (Fed. Cir. 1983)
  - Affirmative duty of due care to avoid infringement after receiving actual notice of an adverse patent
  - Duty to "seek and obtain competent legal advice from counsel before the initiation of any possible infringing activity"
  - Negligence standard

Leverage

Opinions of Counsel

- Clearance/Freedom to Operate
- Patentability
- Due Diligence
- Pre-Litigation
- Infringement
- Validity

What Makes Infringement "Willful?"

- What if I have a patent in my file but really never looked at it?
- What if I looked at it but never appreciated its significance?
- What if I appreciated what I thought was a minor risk so I did nothing?
- What if the patent owner sent me a warning letter?

Opinions of Counsel—Underwater Devices

- BUT, Opinion of Counsel Must Be
  - Timely
  - Independent and competent

- Opinion of Counsel Did Not Save M-K
  - Untimely
  - In-house counsel
  - Did not review file history
  - Conclusory statements

- Discovery
  - Compliance with duty of care
  - Attorney deposition

Duty of Due Care—Totality of Circumstances

- Totality of Circumstances Considered In Determining Whether Infringer Satisfied Affirmative Duty of Due Care
  - Presence/absence of timely opinion of counsel
    - Absence of opinion did not mandate finding of willfulness *Rolls-Royce Ltd. v. GTE Valeron Corp.*, 800 F.2d 1101 (Fed Cir. 1986)
  - Deliberate copying/attempt to design around
  - Infringer's behavior as a party in litigation
  - Infringer's size and financial condition
  - Closeness of case
  - Duration of infringement
  - Remedial actions taken
  - Infringer's motivation for harm
  - Infringer's attempt to conceal misconduct
  - Any other factors tending to show good faith or lack thereof

Duty of Due Care: Opinions of Counsel
Adverse Inference

- Pre *Knorr-Bremse*
  - Accused infringer silent or asserts AC privilege
    - Creates inference that no opinion was obtained or, if obtained, was a negative opinion
  - Dilemma
    - Produce opinion, waive privilege; or
    - Maintain privilege, suffer adverse inference
    - Seek in camera review or bifurcate and stay willfulness
      - Often denied

Demise of Adverse Inference: *Knorr-Bremse*

- Reaffirmed *Underwater Devices* Duty of Due Care.
- Reaffirmed totality of circumstances test.
- BUT overruled negative inferences.
- Judge Dyk dissent:
  - Would have overruled duty of due care
  - Inconsistent with Supreme Court punitive damages cases.

Knorr-Bremse Systeme Fuer Nutzfahrzeuge Gmbh v. Dana Corporation, 383 F.3d 1337, 1344-46 (Fed. Cir. 2004) (*en banc*)

Willfulness Bar Is Raised – *Seagate*

- Factual Background
  - Seagate disclosed opinions of outside counsel (who was not trial counsel), rendered after suit was filed, to defend against willfulness
  - Patentee moves to compel communications with any counsel, including trial counsel, concerning issues in produced opinions and seeks depositions of counsel.

In re Seagate Technology, LLC, 497 F.3d 1360 (Fed. Cir. 2007) (*en banc*)

Willfulness Bar Is Raised – *Seagate*

- District Court Ruling
  - Seagate waived AC privilege for all communications with any counsel concerning issues in produced opinions
  - Waiver extended from first knowledge of patents up until alleged infringement stopped
  - Work product protection for communications to Seagate also waived
  - In camera review of trial strategy documents, but advice of trial counsel to Seagate that undermined reasonable reliance on produced opinions would warrant disclosure

Willfulness Bar Is Raised—*Seagate*

- Seagate Appeals
  - Seagate petitioned for mandamus to block production of trial counsel opinions and deposition of trial counsel
  - Federal Circuit stayed discovery and sua sponte orders *en banc* review of petition

Willfulness Bar Is Raised – *Seagate*

- *En Banc* Order
  - Should reliance on advice of counsel defense waive AC privileged communications with trial counsel?
  - What effect does any such waiver have on Work-Product immunity?
  - Given impact on waiver issues, should *Underwater Devices* affirmative duty of care standard be reconsidered?

Willfulness Bar Is Raised – *Seagate*

- *Underwater Devices'* Duty of Care Standard Overruled
  - Adopted "when widespread disregard of patent rights was undermining the national innovation incentive."
  - Contrasted *Underwater Devices* standard with "willfulness" in civil law context
    - Duty of care akin to negligence standard
    - BUT "willfulness" in civil context is akin to recklessness
    - Supreme Court precedent, outside patent law, construed statutory recovery of punitive damages for "willful" violations as requiring "reckless" behavior
  - *Seagate* overrules *Underwater Devices* - threshold for willfulness is too low

Willfulness Bar Is Raised – *Seagate*

- *Seagate's* New Two Step Willfulness Inquiry
  - STEP 1
    - Clear and convincing evidence of "**objective recklessness**," namely, that the "infringer acted despite an **objectively high likelihood that its actions constituted infringement of a valid patent**"
    - Accused infringer's state of mind not relevant to this objective inquiry

Willfulness Bar Is Raised – *Seagate*

- *Seagate's* New Two Step Willfulness Inquiry
  - STEP 2 (Reached only if threshold objective standard is satisfied)
    - Patentee must also show that "this objectively-defined risk (determined by the record developed in the infringement proceeding) was either **known or so obvious that it should have been known to the accused infringer"**
    - Court declined to elaborate on Step 2, but expected "the standards of commerce would be among the factors a court might consider"
    - Accused infringer's **subjective state of mind** relevant to Step 2

Willfulness Bar Is Raised – *Seagate*

- *Seagate's* Additional Comments on Willfulness
  - Willfulness Based on Pre-litigation Conduct
    - Most typical situation
    - Patentee must have good faith basis for alleging in complaint willful infringement
    - Assertions of willful infringement in original complaint must be grounded exclusively in accused infringer's pre-filing conduct
    - Opinions received after suit was filed may be of marginal value

Willfulness Bar Is Raised – *Seagate*

- *Seagate's* Additional Comments on Willfulness
  - Willfulness Based Solely On Post-Filing Conduct
    - Remedy for Post-filing conduct is a PI
    - Failure to file PI should preclude patentee from accruing enhanced damages based solely on post-filing conduct
    - If patentee loses PI because of substantial question about invalidity or infringement, then willfulness based solely on post-filing conduct likely will also fail

New Law Affecting *Seagate* Analysis

- *Bard Peripheral Vascular, Inc. v. W.L. Gore & Assocs., Inc.*, 682 F.3d 1003 (Fed. Cir. 2012)
  - Court holds for first time since *Seagate* that threshold objective prong of the willfulness standard…is a question of law . . . subject to *de novo* review.

Willfulness Bar is Further Raised—*Bard*

- Judge remains final arbiter on whether defense was reasonable, even when issue sent to the jury.
  - Based solely on record in infringement case.

- Under *Seagate*, the objective prong is generally not met where accused infringer relies on a reasonable defense.
  - *See, e.g., Spine Solutions, Inc. v. Medtronic Sofamor Danek USA, Inc.*, 620 F.3d 1305, 1319 (Fed. Cir. 2010).

Willful Infringement Allegations are Popular

- Alleged in nearly every patent case (e.g., >90%)
- Usually decided by jury, if requested
- Judge decides any enhancement

Moving Forward: What *Seagate* HAS Done

- While more than 90% of complaints continue to allege willful infringement,
- Patentee success rate has dropped

Willful Infringement Decisions

Year(s)	Patentee Success Rate
2000-2007 (Pre-*Seagate)*	≈60%
2007-2009 (Post-*Seagate*)	≈43%

Percentages calculated from data at patstats.org

Moving Forward: What *Seagate* HAS NOT Done

- *Seagate* has not rendered opinions of counsel insignificant
  - Producing an opinion of counsel
    - Useful in defeating a patentee's effort to prove willful infringement and enhanced damages
  - Failing to obtain an opinion of counsel
    - In many jurisdictions, still weighs in the analysis as to whether infringement was willful
    - Can effect trial court's decision to enhance damages

Post-*Seagate*: Producing an Opinion

- A "competent" opinion of counsel can show that an alleged infringer was not "objectively reckless"
  - Obtained and relied on in good faith
  - Conclusion of noninfringement OR invalidity can suffice

> "[A] competent opinion of counsel concluding either [noninfringement] or [invalidity] would provide a sufficient basis for the [deemed infringer] to proceed without engaging in objectively reckless behavior…"

Finisar Corp. v. DirecTV Group, Inc., 523 F.3d, 1339 (Fed. Cir. 2008)

Post-*Seagate*: Failing to Obtain an Opinion

- Case law is split as to whether lack of an opinion of counsel is still a factor in determining willful infringement.
  - Many courts have concluded that, while there is no longer any "adverse inference" from the failure to obtain opinion of counsel, it is still a factor to be considered in the "totality of the circumstances" approach
  - A number of courts, however, have interpreted *Seagate* differently, concluding that lack of opinion of counsel cannot be considered at all

Failing to Obtain an Opinion is NOT Relevant

- Some courts have refused to consider evidence pertaining to opinions of counsel
  - "[I]n light of *Knorr-Bremse* and *Seagate*, the Court believes that defendant was under no obligation to obtain an opinion of counsel, and plaintiff is precluded from mentioning evidence related to defendant's lack of opinion of counsel." *World Wide Stationery Mfg. Co. v. U.S. Ring Binder*, 2009 LEXIS 113169, at *6 (E.D. Mo. 2009).
  - "[I]n [concluding that plaintiff cannot meet the high standard of showing willful infringement by clear and convincing evidence,] I have not taken into account plaintiff's allegation that defendants never consulted counsel before acting as they did. Whether they did or not is irrelevant to determining reckless disregard for plaintiff's rights."

    Ricoh Co. v. Quanta Computer, Inc., 2009 WL 3925453, at *1 (W.D. Wis. 2009).
  - "Alloc asked the Court to consider the fact that Balterio never obtained an opinion from legal counsel stating that its Click Xpress panels did not infringe on other patents. The *Seagate* court, however, did away with this requirement by holding that 'there is no affirmative obligation to obtain opinion of counsel.'"

    Alloc, Inc. v. Norman D. Lifton Co., 653 F. Supp. 2d 469, 476 (S.D.N.Y. 2009).

Failing to Obtain an Opinion IS Relevant

- Other courts still consider it in the willfulness analysis
  - "The seminal question is whether a jury, after *Seagate*, can hear testimony that a defendant did not seek advice of counsel in determining whether, under the totality of the circumstances, any infringement by the defendant was willful. This court holds that it can, again, as long as no adverse inference is drawn as to what the advice may have been."

    Tyco Healthcare Group, LP v. Applied Med. Res. Corp., 2009 WL 5842063, *3 (E.D. Tex. 2009)
  - The Court agrees with what appears to be the majority view *post-Seagate* that lack of opinion of counsel, while not giving rise to an adverse inference, is still a factor that the jury can consider when applying the 'totality of the circumstances' approach with respect to willfulness of infringement."

Presidio Components Inc. v. American Tech. Ce-Ramics, 723 F.Supp.2d 1284, 1324 (S.D. Ca. 2010)

Failing to Obtain an Opinion IS Relevant to Second Prong

- The presence or absence of an opinion may have little relevance to the question of whether there was an "objectively high likelihood of infringement," BUT

- Courts have held that it is relevant to the second prong – whether an alleged infringer knew or should have known of the objectively high risk of infringement.
  - "*Seagate* does not foreclose the possibility that the trier of fact could consider the failure to seek an opinion of counsel when determining whether the second prong of the willfulness test is satisfied, so long as it does not automatically draw an adverse inference from such a failure."

    Tyco Healthcare, 2009 WL 5842063, at *2 n.3; *see also Krippelz v. Ford Motor Co.*, 670 F. Supp. 2d 806, 812 (N.D. Ill. 2009)

Failing to Obtain an Opinion IS Relevant to Second Prong

- "Standards of Fair Commerce"
- May allow for a finding of willfulness if an infringer fails to obtain an opinion of counsel where a reasonable, prudent commercial entity would have sought an opinion
  - "The fundamental issue remains the reasonableness, or in turn the culpability, of commercial behavior that violates legally protected property rights"
  - *Seagate*, 497 F.3d at 1385 (Newman, J., concurring)
- Especially relevant to the second prong of the willfulness inquiry
  - "While the court is mindful of the *Seagate* rule that there is no affirmative obligation to obtain the advice of counsel, Goldstein's opinion, [that, in the medical devices industry, the general practice is to obtain a legal opinion on known patents], is relevant to whether or not, under the totality of the circumstances, Applied knew or should have known of the objectively high likelihood that its actions constituted infringement of a valid patent"
  - *Tyco Healthcare*, 2009 WL 5842063, at *3

"No Affirmative Obligation to Obtain an Opinion of Counsel"

- Some courts have noted the absence of an opinion but found no willfulness based on other factors
  - Closeness of the case
    - Strength and reasonableness of noninfringement and/or invalidity positions
  - Immediate technical investigations
  - Reasonable attempts to design around the patents
  - Patentee's delay in pursuing claims of infringement

Enhanced Damages—Read Factors

- "[T]he standard for deciding whether-and by how much-to enhance damages is set forth in *Read Corp.*, not *Seagate*" *i4i Ltd. P'ship v. Microsoft Corp.*, 598 F.3d 831, 859 (Fed. Cir. 2010).

1. Whether the infringer deliberately copied the ideas or design of another,
2. Whether the infringer, when he knew of the other's patent protection, investigated the scope of the patent and formed a good-faith belief that it was invalid or that it was not infringed,
3. The infringer's behavior as a party to the litigation,
4. The defendant's size and financial condition,
5. The closeness of the case,
6. The duration of the defendant's misconduct,
7. Remedial action by the defendant,
8. The defendant's motivation for harm; and
9. Whether the defendant attempted to conceal its misconduct.

Read Corp. v. Portec, Inc., 970 F.2d 816, 826-27 (Fed. Cir. 1992)

Enhanced Damages and No Opinion

- The second *Read* factor
  - Whether the infringer, when he knew of the other's patent protection, investigated the scope of the patent and formed a good-faith belief that it was invalid or that it was not infringed
    - **Failing to obtain an opinion of counsel can be used to show that an infringer did not adequately investigate the patent**

      

      Significant impact on whether damages are enhanced
  - "Although Defendants are correct [that they were under no obligation to obtain an opinion of counsel to avoid willfulness], their failure to obtain an opinion until after this case was filed speaks to the adequacy of their investigation…"

I-Flow Corp. v. Apex Med. Techs., Inc., 2010 U.S. Dist. LEXIS 1021, at *6 (S.D. Cal. 2010)

Enhanced Damages and No Opinion

- *i4i Ltd. P'ship. v. Microsoft Corp.*, 598 F.3d 831 (Fed. Cir. 2010)
  - No evidence that Microsoft deliberately copied, BUT
  - Enhanced damages awarded where Microsoft, after learning of the patent, failed to obtain an opinion of counsel
  - (5 of 9 *Read* factors supported enhancement)
- *I-Flow Corp.*, 2010 U.S. Dist. LEXIS 1021 (S.D. Cal. 2010)
  - Enhanced damages awarded where infringer relied upon technical employees' conclusory opinions of noninfringement and did not obtain an opinion of counsel until after the case was filed
  - (2 of 9 *Read* factors supported enhancement)

Enhanced Damages and No Opinion

- *Creative Internet Adver. Corp. v. Yahoo! Inc.*, 689 F.Supp.2d 858 (E.D. Tex. 2010)
  - Enhanced damages awarded where General Counsel for infringer communicated noninfringement positions to patentee's counsel but failed to obtain a formal written or oral opinion of counsel
  - "In sum, the Court finds that Yahoo's failure to seek the advice of outside counsel particularly concerning. When combined with the superficial investigation conducted by [General Counsel] , the Court concludes that Yahoo did not make a good faith effort to investigate the infringement charges before it. For these reasons, the weight of the evidence favors enhanced damages." *Id*. at 866.
  - (5 of 9 *Read* factors supported enhancement)

No Enhancement of Damages and No Opinion

- Not all failures to obtain an opinion of counsel will lead to enhanced damages if the failure is outweighed by other factors

Emcore Corp. v. Optium Corp., Civ. Action No. 7-326 (W.D. Pa. Jan. 15, 2010)

  - Although no opinion of counsel
    - there was only circumstantial evidence of copying,
    - the infringer did not litigate in bad faith,
    - the case was close "on all issues, including willfulness,"
    - the infringer ceased manufacturing the accused product during the pendency of the litigation.

What if an Accused Infringer Chooses Not to Produce an Opinion?

- District courts have held that
  - Neither party may argue aspects of opinions of counsel to the jury
  - The jury will not be instructed to consider any aspects relating to opinions of counsel
    - *See, e.g., Spectralytics, Inc. v. Cordis Corp.*, No. 05-CV-1464, 2009 U.S. Dist. LEXIS 114575 (D. Minn. Jan. 13, 2009); *Telcordia Tech., Inc. v. Lucent Tech., Inc.*, Nos. 04-875, 04-876, 2007 WL 7076662 (D. Del. Apr. 27, 2007).

Summary of Willful Infringement

- So what have we learned about willful infringement?

Impact of *Seagate* and *Bard*

- Willfulness Threshold Raised
  - *Underwater Devices*-affirmative duty akin to negligence standard
  - *Seagate* changed the threshold—"objective recklessness"
  - *Bard*—objective recklessness is a legal determination
- Summary judgment & JMOL, e.g., if close issues would have avoided infringement. *See, e.g., Saffran v. Johnson & Johnson*, C.A. No. 2:07-CV-451 (TJW) (March 31, 2011) (JMOL of no objective recklessness because, inter alia, claim construction close)

Impact of *Seagate* and *Bard* on Opinions of Counsel

- Opinions of Counsel
  - Opinion of counsel still relevant to Step 2 of test, namely, whether objectively defined likelihood of infringement of a valid patent was either known or so obvious that it should have been known to accused infringer
  - If opinion of counsel is relied upon to shield pre-litigation conduct, opinion must be timely
  - Pre-*Seagate* case law on competency of opinion is still valid

Questions?

Thank you and Speaker Information

Laura Masurovsky chairs Finnegan's Litigation Section. She has successfully represented plaintiffs and defendants in federal and state courts for more than 25 years. She currently litigates complex intellectual property disputes involving a wide range of technologies.

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*** BREAK ***

Please return to your seats by 3:30

Agenda – Session 2

"The Clear Line Blurs – Where is the 'Safe Harbor' of 271(e)(1) after *Classen v. GSK* and *Momenta v. Amphastar*?"

- Jeffrey B. Kushan (Sidley Austin, LLP)

"FTC v. Actavis: Supreme Court Showdown on 'Reverse Payment' Settlements"

- Eric Grannon (White & Case LLP)

"Observations on the Gene Patenting Debate"

- Hans Sauer (Biotechnology Industry Organization)

**********Post-Conference Networking Event**********

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The 271(e)(1) Boundary Blurs

Jeffrey P. Kushan

Washington, D.C.

35 USC 271(e)(1)

- It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention … **solely for uses reasonably related to the development and submission of information** under a Federal law which **regulates** the **manufacture, use, or sale of drugs** or veterinary biological products.

Eli Lilly vs. Medtronic (1990)

- **Testing to support approval of medical device covered by §271(e)(1)**
  - Relied on symmetry of Hatch-Waxman Act to justify conclusion the exemption covered more than drugs
  - Patent term restoration available under § 156 for same range of products that require development and submission of information to secure marketing approval

Eli Lilly v. Medtronic (1990)

- **Scalia writes opinion …**
  - As far as the text is concerned, therefore, we conclude that we have before us **a provision** that somewhat more naturally reads as the Court of Appeals determined, but **that is not plainly comprehensible on anyone's view**.
  - **No interpretation we have been able to imagine can transform 271(e)(1) into an elegant piece of statutory draftsmanship**.

Merck KGaA v. Integra (2005)

- **Key holdings**
  - Testing that generates information **not actually submitted** to FDA is covered by exemption
  - Testing on molecule that does not become the subject of an IND or an NDA is **covered**
  - **Preclinical** testing is **covered**
  - Exemption **not limited to testing to support generic drug applications**

Merck KGaA v. Integra (2005)

- **Scalia again writes opinion, observes**
  - Congress did not limit § 271(e)(1)'s safe harbor to the development of information for inclusion in a submission to the FDA; nor did it create an exemption applicable only to the research relevant to filing an ANDA for approval of a generic drug.
  - **Though the contours of this provision are not exact in every respect**, the statutory text makes clear that it provides a wide berth for the use of patented drugs in activities related to the federal regulatory process.

Proveris v. Innovasystems (Fed. Cir. 2008)

- **Panel (Schall, Bryson, Gajarsa) holds**
  - Use of device for testing nasal spray devices to comply with FDA requirements is **not covered** by § 271(e)(1) exemption
  - The testing device was **not a "product"** regulated by the FDA within meaning of § 156
  - Relied on symmetry of § 156 and 271(e)(1) from *Lilly v. Medtronic*

GSK v. Classen (Fed Cir. 2012)

- **Convoluted path**
  - On remand from Supreme Court, Fed. Cir. holds one patent invalid under § 101
  - Remaining patents take up infringement allegation based clinical trial performed by CDC scientist that proved no correlation between administration schedules of certain vaccines and diabetes
  - Merck found to not be involved, no infringement
  - Fed. Cir considered whether 271(e)(1) shielded clinical trial

GSK v. Classen (Fed. Cir. 2012)

- **Newman writes panel opinion, holds**
  - "Classen is correct, for § 271(e)(1) provides an exception to the law of infringement in order to expedite development **of information for regulatory approval of generic counterparts** of patented products. The **statute does not apply to information that may be routinely reported to the FDA**, **long after marketing approval has been obtained."**
  - **Basis? The legislative history of the HW Act.**
  - **Extensive concurrence by Rader.**

GSK v. Classen (Fed. Cir. 2012)

- **Reconciling with Merck KGaA?**
  - In contrast, the Biogen and Glaxo activities charged with infringement are **not related to producing information for an IND or NDA**, and **are not a "phase of research" possibly leading to marketing approval.**

GSK v. Classen (Fed. Cir. 2012)

- **Moore dissent first contests pre/post line**
  - "Accordingly, I conclude that the safe harbor extends to all uses that are reasonably related **to submitting** any information under the FDCA, including information regarding post-approval uses."
    - ["… **developing and** submitting…"]?
  - "The language Congress chose to enact and that was signed into law by the President **is plain on its face**."

GSK v. Classen (Fed. Cir. 2012)

- **Moore dissent next finds certain conduct shielded by exemption**
  - "I agree that … the alleged participation by GSK and Biogen in **studies evaluating risks associated with different vaccination schedules is reasonably related to their requirement to review and report adverse information to the FDA**."

GSK v. Classen (Fed. Cir. 2012)

- **Moore draws line on infringing conduct**
  - The general administration of drugs or vaccines **is not reasonably related to post-approval reporting requirements**. … The fact that GSK or Biogen **would have to report to the FDA any adverse reaction** after administering a vaccine **does not mean the administration itself is noninfringing**.

Momenta v. Amphastar (Fed. Cir. 2012)

- **Patent concerns method of producing certain composition of heparins**
  - Momenta was first generic version of Lovenox on the market, sues first filer Amphastar for infringement
  - Contends Amphastar must use its method to meet FDA requirements for product profile in product monograph
  - Momenta wins at district court

Momenta v. Amphastar (Fed. Cir. 2012)

- **Moore writes majority opinion, Rader dissent**
  - "**Congress could not have been clearer in its choice of words**: as long as the use of the patented invention is solely for uses 'reasonably related' to developing and submitting information pursuant to 'a Federal law' regulating the manufacture, use or sale of drugs, it is not 'an act of infringement.'"
  - "This broad language **unambiguously** applies to submissions under any federal law, providing that law "regulates the manufacture, use or sale of drugs."

Momenta v. Amphastar (Fed. Cir. 2012)

- **Amphastar batch manufacturing records found to be covered by exemption**
  - "'Reasonably related' **does not mean that the use of the patented invention must necessarily result in submission** of information to the FDA.."
  - FDA requirement for Amphastar to retain batch records for one year after batch expiration for possible FDA inspection "satisfies the requirement that the uses be reasonably related to the development and submission of information to the FDA."

Momenta v. Amphastar (Fed. Cir. 2012)

- **Reconciling GSK v. Classen**
  - The CDC studies "themselves were not mandated by the FDA, but any vaccine license holder was required to report to the FDA 'adverse experience information' such as adverse side effects, it acquired as a result of the vaccine studies."
  - Classen holds "the scope of the safe harbor provision does not extend to 'information that may be routinely reported to the FDA, long after marketing approval has been obtained"
    - Such as batch records associated with ongoing manufacturing of a product?

Momenta v. Amphastar (Fed. Cir. 2012)

- **Dancing around *Classen***
  - "This case fits well within *Classen* because the information submitted is necessary both to the continued approval of the ANDA and to the ability to market the generic drug."
  - Requirement to retain records = "submission"
  - Classen did not impose a pre/post approval line for eligibility for exemption

Momenta v. Amphastar (Fed. Cir. 2012)

- **Navigates the "solely" language as well**
  - "Solely" requirement not a problem either because "'Solely … does not place any other restriction on when the patented invention may be used without infringing."
  - 271(e)(1) language provides exemption "…solely for uses reasonably related to developing and submitting information…"
    - Past cases hold that **information** generated by an exempted use **may** be used for **other purposes**, not that other uses are also authorized!

Momenta v. Amphastar (Fed. Cir. 2012)

- **No requirement for "equilibrium" in HW**
  - "…the dissent suggests that we must reject any disequilibrium between sections 201 and 202 of the Hatch-Waxman Act, that is, the safe harbor should not be available unless a patent term extension is also available. … That is not correct."
    - But that was a central justification of *Proveris* (2008) for determining that a patent was not subject to the 271(e)(1) exemption

Momenta v. Amphastar (Fed. Cir. 2012)

- **Rader dissents vigorously**
  - Points out the Supreme Court had observed text of § 271 is not "plainly comprehensible"
  - Amphastar's infringing conduct is "**not solely** for developing and submitting information to the FDA. Instead, Amphastar uses this method for the purpose of manufacturing a product to sell on the market in commerce."
    - Extensive legislative history emphasizes exemption does not extend to **commercial marketing** activities
  - Retained records are **not submitted** to FDA.

GSK v. Classen (Fed. Cir. 2012)

- **USG Brief in Cert Petition Phase**
  - "The court of appeals **erred** in stating that Section 271(e)(1)'s safe harbor **encompasses only activities undertaken to obtain the FDA's pre-marketing approval of generic products**."
  - Cites with approval *Merck KGaA* holding that:
    - "There is simply no room in the statute for excluding certain information from the exemption on the basis of the phase of research in which it is developed or the particular submission in which it could be included."

GSK v. Classen (Fed. Cir. 2012)

- **USG points to Momenta as solving problem**
  - There is no longer any practical need for this Court's intervention in light of the Federal Circuit's subsequent decision in *Momenta* … [which] … held that post-approval studies performed for the FDA 'fall within the scope of § 271(e)(1) safe harbor…"

GSK v. Classen (Fed. Cir. 2012)

- **USG describes regulatory scenarios where information must be generated to satisfy FDA requirements <u>after original approval</u>**
  - New indications (voluntary conduct)
  - Fast track approvals contingent on post-approval marketing
  - Pediatric investigations
  - Clinical trials if safety/efficacy concerns arise after original marketing

GSK v. Classen (Fed. Cir. 2012)

- **USG correctly frames "solely" language**
  - Stated that if a particular use is reasonably related to development and submission of information to the FDA, then it falls within exemption "even if that experiment **also advances** other commercial objectives, such as product development."
  - Post-approval conduct requires more thorough evaluation to distinguish shielded vs. unshielded uses
    - The term "**development**" implies **more than merely the collection of information incidental to commercial transactions**

GSK v. Classen (Fed. Cir. 2012)

- **USG brief highlights *Proveris* as limiting scope of 271(e)(1)**
  - "…the Federal Circuit has since held that 271(e)(1) does not exempt from infringement claims the use of a patented research apparatus."
- **USG concludes that this is not the right case for the Court to take on**
  - Facts may not be good to frame issues

Where Is the Line Now?

- **Unresolved issues -- does 271(e)(1) shield**
  - Conduct **after** original approval
  - Generating information to comply with FDA requirements vs. “development and submission of information” pursuant to an FDA regulatory scheme
  - Conduct generally if some of it is required by FDA (vs. allowing use of information generated by shielded conduct for other purposes)
- **Pending petition for cert filed by Momenta on February 15, 2013**

WHITE & CASE

Federal Trade Commission v. Actavis, Inc., et al.

Supreme Court Showdown on "Reverse Payment" Settlements

NJIPLA 2013 Patent Litigation Seminar
March 13, 2013

ERIC GRANNON

Overview

I. Case Law Leading up to Circuit Split

II. The *AndroGel* Settlements

III. MMA Remedial Amendments to Hatch-Waxman

IV. Arguments in Supreme Court

V. Q&A

What is a “Reverse Payment” Settlement?

- Innovator and generic settle Paragraph-IV ANDA litigation
  - Generic granted non-immediate entry, usually substantially in advance of patent expiration
  - Innovator provides “anything of value” to generic beyond early entry
    - Any contemporaneous business transaction
    - “No AG” provision (exclusive license)
- FTC wins labeling contest with “Pay for Delay”

Asymmetrical Risks of Paragraph-IV Litigation

- **Hatch-Waxman's "highly artificial act of infringement" creates asymmetrical risks between innovators and generics, incentivizing reverse-payment settlements even when the patent holder is confident.**
- Illustrating this asymmetry, the FTC reports:
  - "[F]or a drug with [annual] brand sales of $130 million, a generic that does not anticipate [authorized generic] competition will expect a patent challenge to be profitable if it has at least a 4 percent chance of winning [a Paragraph-IV challenge]."
    - FTC, *Authorized Generic Drugs: Short-Term Effects and Long-Term Impact* iii n.7 (2011).

Case Law on "Reverse Payment" Final Settlements

- "Scope of the patent" approach requires
  - "consideration of [1] the scope of the exclusionary potential of the patent, [2] the extent to which these provisions of the Agreements exceed that scope, and [3] the anticompetitive effects thereof."
    - *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1312 (11th Cir. 2003).

Scope of the Patent Approach Unanimous from 2003-2012

- *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294 (11th Cir. 2003).
- *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005).
- *Andrx Pharms., Inc. v. Elan Corp.*, 421 F.3d 1227 (11th Cir. 2005).
- *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187 (2d Cir. 2006).
- *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323 (Fed. Cir. 2008).
- *Arkansas Carpenters Health & Welfare Fund v. Bayer AG*, 604 F.3d 98 (2d Cir. 2010).
- *FTC v. Watson Pharmaceuticals, Inc.*, 677 F.3d 1298 (11th Cir. 2012).
- *In re K-Dur Antitrust Litig.*, 686 F.3d 197 (3d Cir. 2012).

Third Circuit Adopts FTC's "Quick Look" Presumption

- "[T]he finder of fact must treat any payment from a patent holder to a generic patent challenger who agrees to delay entry into the market as *prima facie* evidence of an unreasonable restraint of trade, which could be rebutted by showing that the payment (1) was for a purpose other than delayed entry or (2) offers some pro-competitive benefit."
  - *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 218 (3d Cir. 2012).

AndroGel Settlements

- **Innovator:** Solvay Pharmaceuticals (acquired by Abbott now AbbVie)
- **First-Filer:** Actavis (f/k/a Watson Pharmaceuticals)
- **Second-Filer:** Par Pharmaceutical Companies & Paddock Laboratories
  - Pre-MMA Paragraph-IV litigation ensued in 2003
  - Settled in 2006 in N.D. Ga. under *Schering-Plough* decision
  - Five years early entry
  - Contemporaneous business transactions
  - FTC sues in California in 2009

FTC Ignores MMA's Remedial Amendments

- **Having lobbied Congress to pass the MMA, the FTC's merits brief oddly ignores the MMA Amendments entirely, which included, among other remedial changes:**
  - forfeiture of 180-day exclusivity (ending "bottlenecking")
  - shared 180-day exclusivity for multiple "first filers"
  - specified antitrust penalty (180-day forfeiture)
  - antitrust savings clause (expressly disclaiming "presumption")

The MMA's Antitrust Savings Clause

- **Sec. 1117. SAVINGS CLAUSE.**
  - "Any action taken by the [DOJ] or the [FTC], or any failure of the [DOJ] or the [FTC] to take action, under this subtitle shall not at any time bar any proceeding or any action with respect to any agreement between a brand name drug company and a generic drug applicant, or any agreement between generic drug applicants, under any other provision of law, ***nor shall any filing under this subtitle constitute or create a presumption of any violation of any competition laws***."
    - 21 U.S.C. 355 note (emphasis added).

MMA Amendments Reduced Incentives for Reverse Payments

- The MMA's remedial changes have reduced incentives for reverse payments (as the United States twice predicted in prior Supreme Court briefs), resulting in declining rates throughout the years when the circuits unanimously applied the scope-of-the-patent approach.
- **Congress chose to reduce incentives for reverse payments, rather than to prohibit reverse payments or enact a "presumption" against them.**

Declining Rates of "Reverse Payments"

Overview of Final Settlements

(2004-2011)

Fiscal Year	2004	2005	2006	2007	2008	2009	2010	2011
Final Settlements	14	11	28	33	66	68	113	156
Potential Pay-for-Delay	0	3	14	14	16	19	31	28
	0%	27%	50%	42%	24%	28%	27%	18%

From presentation by Bradley S. Albert, Deputy Assistant Director, FTC, *"Are Reverse Payments Dead?"* program sponsored by ABA Section of Antitrust Law, Healthcare and Pharmaceuticals Committee (Nov. 10, 2011).

"Reverse Payment" Rate Only 15% in FY2012

- FTC's FY2012 report indicates 140 "final settlements," of which FTC says 40 were "potential pay-for-delay"
  - In 19 of the 40, only "compensation" was a "No AG" provision
- A recent decision applying the Third Circuit's *K-Dur* rule held that such settlements involving a brand name's agreement not to launch an authorized generic are *not* "pay-for-delay."
  - *In re Lamictal Direct Purchaser Antitrust Litig.*, No.2:12-cv-00995-WHW-CLW, 2012 WL 6725580, at *6 (D.N.J. Dec. 6, 2012).

FTC Never Has Challenged a Post-MMA Settlement

- Beyond the decline in reverse-payment rates post-MMA, the government has *not* challenged *any* alleged reverse-payment settlement governed by post-MMA law.
  - See *Overview of FTC Antitrust Actions in Pharmaceutical Services and Products* 13-19 (Sept. 2012).

Pending Legislation Proposes Presumption FTC Seeks

- Pending legislation would change the antitrust standard for Hatch-Waxman settlements in FTC suits under the FTC Act (*i.e.*, not private cases):

> (2) **Presumption**.—
>
> (A) In General.— . . . [A]n agreement shall be presumed to have anticompetitive effects and be unlawful if—
>
> (i) an ANDA filer receives anything of value; and
>
> (ii) the ANDA filer agrees to limit or forego [sic] research, development, manufacturing, marketing, or sales of the ANDA product for any period of time.

  - S. 214, 113th Cong. § 3(2) (introduced Feb. 4, 2013).

FTC's Novel Rule Turns on Appraising Parties' Consideration

- Besides ignoring the patent, the FTC seeks an unprecedented departure from traditional antitrust principles, which assess the lawfulness of *restraints*, to a novel rule that instead assesses the consideration underlying the agreement.
- In other words, the same restraint may be upheld or condemned under the FTC's rule depending on whether the amount of consideration was minimal or substantial.
- In 120 years, no antitrust rule has turned on appraising parties' consideration.

Hatch-Waxman Does Not Favor Litigation over Settlement

- "[G]eneric companies are successful, thus able to market the generic product before patent expiration, in just 48 percent of cases [that have gone to trial]. But when factoring in settlements, generics are successful in bringing the generic product to market before patent expiration in 76 percent of cases."
  - Generic Pharm. Ass'n, *Generic Drug Savings in the U.S.*, at 7 (4th ed. 2012).

FTC's Key Concession #1

- FTC's rule would cause fewer cases to settle:
  - "To be sure, in some paragraph IV litigation that might otherwise have been settled through reverse-payment agreements, a rule discountenancing reverse payments may cause the parties to litigate to judgment." FTC Br. 40.

FTC's Rule Challenges Presumption of Validity

- The crux of the FTC's argument is that patents confer merely "probabilistic" rights and, because the FTC suspects many "weak" patents exist, patent settlements require judicial appraisal beyond the scope of the patent:
  - "[T]he scope-of-the-patent approach allows the patentee to purchase the same period of exclusivity that a successful infringement suit would produce, ***even if all would concede that the patentee had little likelihood* of *prevailing*** in the infringement litigation." FTC Br. 44 (emphasis added).
- The FTC never explains how to establish this Greek chorus of agreement on the patent's slim chances if the case is *not* "objectively baseless."
  - *Prof'l Real Estate Investors v. Columbia Pictures (PRE)*, 508 U.S. 49, 60-61 (1993).

FTC's Rule Challenges Presumption of Validity

- *Microsoft v. i4i*, 131 S. Ct. 2238, 2252 & n.11 (2011):
  - "Congress has amended the patent laws to account for concerns about 'bad' patents, including by expanding the reexamination process to provide for *inter partes* proceedings. Through it all, the evidentiary standard adopted in [35 U.S.C.] § 282 has gone untouched."

FTC's Key Concession #2

- FTC concedes that attempting a more fine-tuned antitrust assessment of patent merits than *PRE*'s sham standard would be "doctrinally anomalous and likely unworkable in practice." FTC Br. 53.
- **For antitrust purposes, there are no "weak" patents; there are sham patents and non-sham patents.**

"Quick Look" Categorical Presumption of Unlawfulness is Doctrinally Unsound

- The Supreme Court's last "quick look" case rejected the FTC's quick look at an advertising restriction imposed by a dentists' association, holding:
  - "What is required, *rather*, is an enquiry meet for the case, looking to the circumstances, details, and logic of a restraint."
    - *California Dental Ass'n v. FTC*, 526 U.S. 756, 781 (1999) (emphasis added).
- Even dissenters agreed with this "unobjectionable principle[]."
    - *Ibid.* (Breyer, J., concurring in part and dissenting in part).

“Quick Look” Approach is Inappropriate

- ***FTC v. Indiana Federation of Dentists*****,** 476 U.S. 447, 458-59 (1986) (evaluating group boycott by dentists’ association under “quick look” instead of *per se* rule: “[W]e decline to resolve this case by forcing the Federation’s policy into the ‘boycott’ pigeonhole and invoking the *per se* rule.”);

- ***NCAA v. Board of Regents***, 468 U.S. 85, 100-01 (1984) (evaluating broadcasting output limitation imposed by college football association under “quick look” because the “industry [is one] in which horizontal restraints on competition are essential if the product is to be available at all”); and

- ***Nat’l Soc’y of Prof’l Eng’rs v. United States***, 435 U.S. 679, 692-93 (1978) (evaluating engineers’ association’s concerted refusal to discuss prices with potential customers under “quick look” by “analyzing the facts peculiar to the business, the history of the restraint, and the reasons why it was imposed”).

“Quick Look” Approach is Inappropriate

- Each time, the Court considered “quick look” on an *ad hoc* basis for the circumstances of the alleged restraint (each involving unique justifications proffered by different associations).
- The Court never has applied a “quick look” presumption of unlawfulness to *categories* of restraints prospectively.
- **Because the FTC’s presumption effectively can be rebutted only by proof that there was no “reverse payment,” the FTC is really seeking an unprecedented, watered-down category of *per se* violations.**

Precedent Compels Scope of the Patent Approach

I. First Principles

II. *Standard Oil (Indiana) v. United States*, 283 U.S. 163 (1931).

III. *The Cartel Cases*
- *U.S. v. Singer*, 374 U.S. 174 (1963).
- *U.S. v. New Wrinkle*, 342 U.S. 371 (1952).
- *U.S. v. U.S. Gypsum*, 333 U.S. 364 (1948).
- *U.S. v. Line Material*, 333 U.S. 287 (1948).
- *U.S. v. Masonite*, 316 U.S. 265 (1942).

IV. *Walker Process Equip. v. Food Mach. & Chem.*, 382 U.S. 172 (1965).

V. *Prof'l Real Estate Investors v. Columbia Pictures (PRE)*, 508 U.S. 49 (1993).

First Principles (1790)

- U.S. Const. art. I, § 8, cl. 8.
- Act of Apr. 10, 1790, ch. 7, § 1.
- *Bement v. Nat'l Harrow Co.*, 186 U.S. 70, 91 (1902) ("The very object of [the patent] laws is monopoly . . . .").
- **Statutory, time-limited patent monopolies authorize restraints of trade and exclusionary conduct that would violate our antitrust laws absent patent protection.**

First Principles (cont'd)

- Territorial market allocation
  - 35 U.S.C. § 261.
  - *Contra Palmer v. BRG of Ga., Inc.*, 498 U.S. 46 (1990).
- Field-of-use restrictions and customer allocation
  - *Gen. Talking Pictures Corp. v. W. Electric Co.*, 305 U.S. 124 (1938).
- Output limitation
  - *Aspinwall Mfg. Co. v. Gill*, 32 F. 697 (C.C.N.J. 1887).
- Refusals to deal
  - *In re Indep. Service Orgs. Antitrust Litig.*, 203 F.3d 1322 (Fed. Cir. 2000) (upholding Xerox's refusal to sell patented parts to independent service organizations).

Rule of Reason Begins with Scope of the Patent

- The default analysis for alleged restraints of trade is the rule of reason.
  - *Texaco v. Dagher*, 547 U.S. 1, 5 (2006).
- For patent-based restraints, the rule of reason accounts for statutory, time-limited patent monopolies by first inquiring whether the restraint is within the scope of the patent.
  - *E.g.*, *United States v. Line Material*, 333 U.S. 287, 353 (1948) ("If the limitations in a license reach beyond the scope of the statutory patent rights, then they must be tested by the terms of the Sherman Act.").

Standard Oil (1931)

- Patent-infringement litigation and alleged interferences among four primary companies over "cracking" process patents resolved by settlement and cross-licenses.
- Supreme Court rejects government's antitrust claim:
  - "Where there are legitimately conflicting claims or threatened interferences, a settlement by agreement, rather than litigation, is not precluded by the [Sherman] Act."
- Supreme Court so held *despite* the district court's finding that patents were narrow and might *not* have been found infringed.
- Court expressly held that financial consideration frequently is necessary for settlement and is irrelevant to antitrust analysis.

The Cartel Cases (1942-1963)

- None of the five cases cited by the FTC involve a single patentee granting a license to a *patentless* infringer to settle litigation:
  - *Singer* (aggregating competing patents)
  - *New Wrinkle* (patent-pooling and price-fixing)
  - *Gypsum* (requiring royalties on unpatented products)
  - *Line Material* (price-fixing among multiple patentees)
  - *Masonite* (patent-pooling and price-fixing)
- Each case confirms scope of the patent approach.

Walker Process (1965)

- Established a fraudulent-procurement exception for patent enforcement.
  - Other elements under Sherman Act §§ 1-2 still required
- Fraud aside, antitrust liability should *not*
  - "reach monopolies practiced under ***patents that for one reason or another may turn out to be voidable*** under one or more of the numerous technicalities attending the issuance of a patent[.]" 382 U.S. at 180 (Harlan, J., concurring) (emphasis added).
- Nothing in *Walker Process* suggests that a patentee forfeits that protection by settling the very same non-sham litigation.

PRE (1993)

- *PRE* establishes two-tier test for "sham" litigation
  - Objective baselessness
  - Improper subjective motivation
- Objective baselessness is a threshold inquiry required before courts have "occasion to inquire" into propriety of subjective motivation
- Other elements under Sherman Act §§ 1-2 still required

PRE Precludes Antitrust Liability Predicated Solely on Subjective Litigation Views

- For patent litigation with an objective basis and ensuing settlements within the nominal scope of the patent, a rule presuming such settlements unlawful solely based on alleged "reverse payments" would vitiate *PRE*'s holding that parties cannot be subjected to antitrust liability solely predicated on subjective litigation views.
- **The settling parties' *economic* motivations only become relevant if the *legal* infirmity of the settlement is demonstrated by restraints outside the scope of the patent.**

Scope of the Patent Approach ≠ *Per Se* Lawfulness

- The FTC's contention that the scope-of-the-patent approach is a rule of *per se* lawfulness overlooks the FTC's own pending *Provigil* enforcement action, the *AndroGel* private suits, *K-Dur*, and numerous other challenges to Hatch-Waxman settlements that survived dismissal under the scope-of-the-patent approach.
- **Far from toothless, the Supreme Court has applied the scope-of-the-patent approach both to uphold and to condemn patent-based restraints of trade.**

Noerr-Pennington Immunity Conferred by Consent Judgment

- Solvay and Watson dismissed their litigation "without prejudice" by filing a stipulation of dismissal "without a court order."
  - Fed. R. Civ. P. 41(a)(1)(A)(ii).
- Solvay and Par/Paddock successfully petitioned the court to enter the Consent Judgment and Order of Permanent Injunction, which:

  i. terminated Solvay and Par/Paddock's litigation "with prejudice";

  ii. enjoins Par/Paddock from selling its generic AndroGel® until 2015 at the latest;

  iii. guarantees Par/Paddock's right to practice the patent after that date; and

  iv. retains continuing jurisdiction to enforce these terms.

Noerr-Pennington/Consent Judgment (cont'd)

- ***United States v. Swift & Co.***, 286 U.S. 106, 115 (1932) ("We reject the argument . . . that a decree entered upon consent is to be treated as a contract and not as a judicial act.").
- ***SEC v. Randolph***, 736 F.2d 525, 528 (9th Cir. 1984) ("A consent decree offers more security to the parties than a settlement agreement where the only penalty for failure to abide by the agreement is another suit.").
- ***Schering-Plough Corp. v. FTC***, 402 F.3d 1056, 1072 (11th Cir. 2005) ("Veritably, the Commission's opinion would leave settlements, including those endorsed and facilitated by a federal court, with little confidence.").

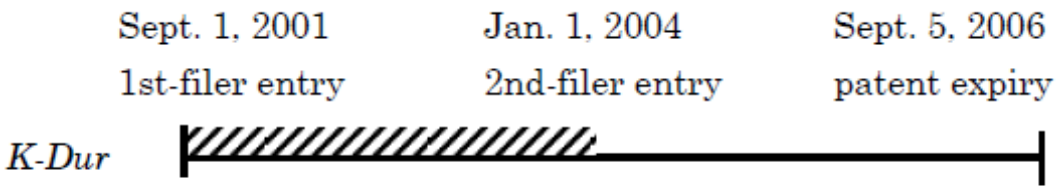
Noerr-Pennington/Consent Judgment (cont'd)

- *California Motor Transport Co. v. Trucking Unlimited*, 404 U.S. 508, 510-11 (1972) (emphasis added):
  - "We conclude that it would be destructive of rights of association and of petition to hold that groups with common interests may not, without violating the antitrust laws, use the channels and procedures of state and federal agencies ***and courts*** to advocate their causes and points of view respecting ***resolution of their business and economic interests*** **vis-à-vis** ***their competitors***."

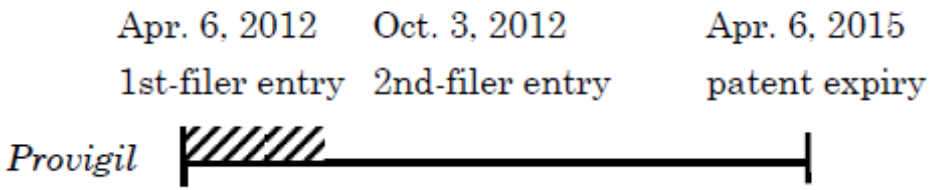
Zero Delay for Second Filer Par/Paddock's Generic Entry

- Even under the FTC's theory that a settlement enabling generic entry before patent expiration may nonetheless cause anticompetitive "delay," a purported delay could only exist if the second filer entered more than 180 days *after* the first filer.
- **In the three reverse-payment cases litigated by the FTC (all involving pre-MMA ANDAs), Par/Paddock is the only second filer that obtained the same entry date as the first filer.**

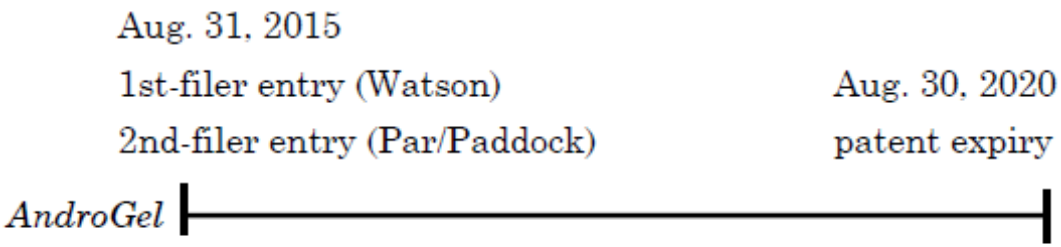
Zero Delay for Second Filer Par/Paddock



"Delay" between first- and second-filer entry = 28 months



"Delay" between first- and second-filer entry = 180 days



"Delay" between first- and second-filer entry = zero

No Better Settlement Possible for Second Filer Par/Paddock

- The FTC dismisses "the competitive consequences of [Par/Paddock's] status as a second filer (as compared to Watson's status as a first filer)" as "an intricate argument."
  - FTC Cert. Reply 9.
- That intricacy derives from the FTC contending that it states an antitrust claim solely by alleging that Par/Paddock "had ample financial incentive to continue to challenge Solvay's patent."
  - FTC Second Amended Complaint ¶ 95.
- **Our antitrust laws do not compel firms to litigate.**

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“*Observations on the Gene Patenting Debate*”

Hans Sauer

Biotechnology Industry Organization

Thank You to our Presenters!

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