

Misleading and Deceptive Conduct: When should it be actionable under Section 2 of the Sherman Act?

Joint DOJ/FTC Workshop on Single Firm Conduct
December 6, 2006

Michael F. Brockmeyer
Frommer Lawrence & Haug LLP
1667 K Street, N.W.
Washington, DC 20006
Phone: 202-292-1545
E-mail: mbrockmeyer@flhlaw.com

Introduction

■ Topics Covered

- Guiding principles
- Abuse of governmental processes through deception in the intellectual property setting
- Tortious conduct

Guiding Principles

Guiding Principles

- A monopolist's aggressive competition on the merits serves consumer welfare even when the monopolist's conduct excludes competitors and maintains the monopolist's monopoly power.
 - Competition on the merits is not exclusionary

Concord Boat Corp. v. Brunswick Corp., 207 F.3d 1039, 1062 (8th Cir.), *cert. denied*, 531 U.S. 979 (2000).

Guiding Principles

- The antitrust laws do not provide a remedy for conduct that violates common law or another statutory scheme and injures competitors unless the conduct substantially harms the competitive process.
 - Such illegal conduct is not “competition on the merits,” but its exclusionary effect often will be insufficient to give rise to a claim under section 2

Brooke Group Ltd. v. Brown & Williamson Tobacco Corp., 509 U.S. 209, 224-25 (1993).

Guiding Principles

- Such illegal conduct “substantially harms the competitive process” when, notwithstanding competitors’ reasonable competitive efforts, the conduct allows durable pricing above competitive levels or there is a “dangerous probability” that supra-competitive pricing will occur.
 - Injured competitors must have attempted to counteract the illegal conduct and have failed
 - Those competitive attempts must have been reasonable, evaluated in the context of a competitive market
 - Harm should be measured by ability to price above competitive levels

Guiding Principles

- Whether “exclusionary” conduct substantially harmed the competitive process must be addressed first before any balancing against a procompetitive justification.

U.S. v. Microsoft Corp., 253 F.3d 34, 45-49 (D.C. Cir.), *cert. denied*, 534 U.S. 952 (2001).

Guiding Principles

- When a monopolist's "exclusionary" conduct is subject to another regulatory scheme designed to promote competition, the antitrust laws should provide a remedy for such conduct only after taking into account the "structure" of the industry involved and the "significance" of the regulatory scheme to the workings of the market.

Verizon Communications Inc. v. Trinko, 540 U.S. 398, 411-12 (2004).

Abuse of Governmental Processes
Through Deception in the
Intellectual Property Setting

Abuse of Governmental Processes

Fraud on the Patent Office

Walker Process, Inc. v. Food Machinery & Chem. Corp., 382 U.S. 172 (1965).

- Food Machinery brought suit against Walker Process for infringement of its patent, and Walker Process counterclaimed that Food Machinery had “illegally monopolized ... commerce by fraudulently and in bad faith obtaining and maintaining ... its patent ... well knowing that it had no basis for a patent.”
 - The alleged fraud was based upon Food Machinery’s swearing before the PTO that it neither knew nor believed that its invention had been in public use in the United States more than one year prior to filing its patent application when, in fact, Food Machinery itself had conducted such use more than one year prior to filing.

Abuse of Governmental Processes

Fraud on the Patent Office

- Majority - Enforcement of a patent procured by fraud on the Patent Office may violate section 2 of the Sherman Act provided the other elements of a section 2 claim are present.
 - “other” elements consist of:
 - “the exclusionary power of the illegal patent claim in terms of the relevant market for the product involved.”
- A finding of “Walker Process” fraud strips a patentee of its immunity from antitrust liability.

Walker Process, 382 U.S. at 177.

Abuse of Governmental Processes

Fraud on the Patent Office

- Concurrence - Justice Harlan clarified the scope of the majority's holding, stating that no cause of action will exist if the plaintiff:
 1. established no more than general invalidity, due to, e.g., obviousness or even "technical fraud"
 2. showed fraudulent procurement, but no knowledge thereof by the defendant
 3. failed to prove the elements of a section 2 claim even though intentional fraud existed
- In closing, Justice Harlan emphasized that "this private antitrust remedy should not be deemed available to reach § 2 monopolies carried on under a nonfraudulently procured patent."

Walker Process, 382 U.S. at 179-80.

Abuse of Governmental Processes

Fraud on the Patent Office

- The Federal Circuit has set forth the elements of a *Walker Process* claim
 1. Attempt to enforce patent
 2. Patent issued because of “intentional fraud”
 3. Attempted enforcement threatens competition in a relevant market
 4. All other elements of a private section 2 claim (i.e., standing and damages)

Unitherm Food Sys., Inc. v. Swift-Echrich, Inc. 375 F. 3d 1341, 1355 (Fed. Cir. 2004), *rev'd on other grounds*, 126 S. Ct. 980 (2006).

Abuse of Governmental Processes

Fraud on the Patent Office

Walker Process - Standard

- Procurement of a patent by fraud is exclusionary conduct actionable under section 2 of the Sherman Act when the patentee possesses monopoly power or there is a “dangerous probability” that the patentee will obtain monopoly power
 - Should apply even before the monopolist has attempted to enforce the fraudulent patent.

Abuse of Governmental Processes

Inequitable Conduct/Sham Litigation

Inequitable Conduct:

- Duty to prosecute patents with candor and good faith, including a duty to disclose information known to the applicants to be material to patentability
- Requires clear and convincing proof of: (1) intent and (2) materiality, and a weighing of the two to determine whether the equities warrant a finding of unenforceability
- “Careful balancing” on a sliding scale: higher intent requires lesser materiality, and vice versa
- Examples of inequitable conduct include:
 - affirmative misrepresentation of a material fact
 - failure to disclose material information
 - submission of false information coupled with intent to deceive or mislead the PTO

Purdue Pharma L.P. v. Endo Pharms., Inc., 438 F. 3d 1123 (Fed. Cir. 2006); 37 C.F.R. § 1.56.

Abuse of Governmental Processes

Inequitable Conduct/Sham Litigation

- The Federal Circuit has discussed the differences between *Walker Process* fraud and inequitable conduct
 - Common law fraud required for *Walker Process* fraud but not for inequitable conduct – “but for” standard
 - Higher showing of both intent and materiality for a *Walker Process* fraud
 - Sliding scale doesn’t slide for *Walker Process* fraud – need heightened showing on both prongs

Nobelpharma AB v. Implant Innovations, Inc., 141 F.3d 1059, 1068-71 (Fed. Cir. 1998).

Abuse of Governmental Processes

Inequitable Conduct/Sham Litigation

Sham Litigation

- A patent owner generally is immune from antitrust liability when it sues to enforce its patent, but enforcement of a patent *may* violate the antitrust laws if the lawsuit is a “sham,” *i.e.*, if it is objectively and subjectively baseless
- “Objectively baseless” suit - “no reasonable litigant could realistically expect success on the merits,” as opposed to a lawsuit in which “a similarly situated reasonable litigant could have perceived some likelihood of success,” or litigant “could have believed it had some chance of winning”
- “Subjectively baseless” suit - bad faith, “attempt to interfere *directly* with the business relationships of a competitor . . . through the use [of] the governmental process”
- The objective prong controls; *i.e.*, regardless of the subjective intent of a litigant, an objectively reasonable effort to litigate cannot be a “sham”

Prof'l Real Estate Investors, Inc. v. Columbia Picture Indus., 508 U.S. 49 (1993).

Abuse of Governmental Processes

Inequitable Conduct/Sham Litigation

- According to the Federal Circuit, *Walker Process* and *Professional Real Estate* “provide alternative legal grounds on which a patentee may be stripped of its immunity from antitrust laws.”

Nobelpharma, 141 F.3d at 1071.

- As such, a defendant in a patent-infringement litigation is free to assert antitrust counterclaims based upon inequitable conduct and sham litigation without relying on *Walker Process* and intentional fraud on the PTO.

See, e.g., Abbott Labs. v. Teva Pharms. USA, Inc., 432 F. Supp. 2d 408, 426-28 (D. Del. 2006) (denying antitrust defendant’s motion to dismiss sham litigation claims predicated upon inequitable conduct).

Abuse of Governmental Processes

Inequitable Conduct/Sham Litigation

Inequitable Conduct/Sham Litigation - Standard

- A monopolist patentee's assertion of a patent in a case where the patent is determined to be unenforceable by reason of the patentee's inequitable conduct may be "exclusionary" only when two conditions are met: (1) the patentee's assertion of the patent constituted sham litigation and (2) the sham litigation substantially harmed the competitive process.
 - The focus should be on the anticompetitive effect of the sham litigation and not on the patentee's conduct before the PTO.

Abuse of Governmental Processes

Improper Listing in the Orange Book

- FDA publication entitled “Approved Drug Products With Therapeutic Equivalence Evaluations,” listing all FDA-approved drug products, both brand name and generic
- The Hatch-Waxman Act requires each holder of an approved NDA (i.e., brand manufacturers) to list in the Orange Book pertinent patents that the NDA holder believes “could reasonably be asserted” against a manufacturer who makes, uses or sells a generic version of the drug prior to expiration of the listed patents (*see* 21 U.S.C. § 355(c)(2))
- Manufacturers of generic drugs must certify against patents listed in the Orange Book, if any, when filing for FDA approval to market their generic products (*see* 21 U.S.C. § 355(j))
- FDA plays only a “ministerial” role in Orange Book listings

Abuse of Governmental Processes

Improper Listing in the Orange Book

- Paragraph IV certifications generate patent infringement suits, despite the lack of actual infringement
 - Generic manufacturer's filing for approval (i.e., ANDA) constitutes a technical act of infringement
 - If the patentee sues within 45 days of receiving a paragraph IV certification, the FDA generally cannot approve the generic manufacturer's product for an additional 30 months (*see* 21 U.S.C. § 355(j))
 - A listing in the Orange Book has pro-competitive attributes because it may encourage a paragraph IV certification - incentive to be first generic filer = 180 days of market exclusivity following FDA approval

Abuse of Governmental Processes

Improper Listing in the Orange Book

- FTC cases
 - *In re Bristol-Myers Squibb Co.*, Nos. 001-0221, 011-0046, 021-0181, 2003 FTC LEXIS 34.
 - FTC’s complaint alleged that BMS “knew”/ “could not [have] reasonably believe[d] that patents were listable” in the Orange Book
 - *In re Biovail Corp.*, No. 011-0094, 2002 FTC LEXIS 24.
 - FTC’s complaint alleged that Biovail “was aware” that the patent listed in the Orange Book did not cover Biovail’s marketed form of Tiazac (in fact, the patent covered a non-approved form of the drug)

Abuse of Governmental Processes

Improper Listing in the Orange Book

Organon Inc. v. Mylan Pharms., Inc., 293 F. Supp. 2d 453 (D.N.J. 2003).

- Organon sued Mylan for patent infringement, invoking the 30-month stay provision of the Hatch-Waxman Act, and Mylan filed antitrust counterclaims
- Mylan's allegations included improper Orange Book listing (off-label use)
- Ruling on improper Orange Book listing:
 - Orange Book listing was not petitioning activity for *Noerr-Pennington* purposes
 - BUT, no antitrust liability attached because "Organon had a reasonable basis for the submission, and therefore, Organon's listing was not improper"

Abuse of Governmental Processes

Improper Listing in the Orange Book

Improper Listing in the Orange Book - Standard

- A brand pharmaceutical company's improper listing of a patent in the Orange Book may be actionable exclusionary conduct under section 2 of the Sherman Act only when the decision to list the patent was "objectively baseless."
 - The test should be objective, looking to whether the brand could have reasonably believed that the listed patent could be asserted against a manufacturer of a generic version of the drug.

Tortious Conduct

Tortious Conduct

Conwood Co., L.P. v. U.S. Tobacco Co., 290 F.3d 768 (6th Cir. 2002), *cert. denied*, 537 U.S. 1148 (2003).

- Conwood and USTC manufacture “moist snuff,” or smokeless tobacco
- Moist snuff products usually sold from manufacturer-owned store racks
 - Provide important point-of-sale advertising, critical in this industry because tobacco advertising is largely prohibited in other advertising media
- Conwood alleged that, beginning in 1990, USTC pursued a strategy to exclude competitors from the moist snuff market
 - Two main categories of anticompetitive activities:
 1. USTC’s abuse of its position as category captain
 2. USTC’s unauthorized removal and/or destruction of Conwood’s (& other competitors’) store racks
- USTC conceded that it had market power in the moist snuff market, and the Sixth Circuit held that its conduct supported the jury’s finding of unlawful maintenance of monopoly power under section 2

Tortious Conduct

Am. Council of Certified Podiatric Physicians & Surgeons v. Am. Bd. of Podiatric Surgery, Inc., 323 F.3d 366 (6th Cir. 2003)

- ABPS sent three mass mailings to ~7,000 hospitals and insurance companies, stating that ABPS was the “ONLY” approved certifying board for podiatric surgery
- Sixth Circuit held that advertising in defendant’s (ABPS) mass mailing did not have anticompetitive effect and affirmed dismissal of plaintiff’s (ACCPPS) section 2 claims
 - “An antitrust claim premised primarily on advertising or speech must overcome a presumption that such advertising or speech had a *de minimis* effect on competition.”
 - CA6 relied on CA9’s ruling in *American Professional Testing Service, Inc. v. Harcourt Brace Jovanovich Legal & Professional Publications, Inc.*, 108 F.3d 1147 (1997), which established a six-part test for rebutting the “*de minimis* presumption”
 - CA6 focused on two required elements, noting that the rest were not necessary:
 1. the advertising was clearly false (no evidence to support this prong), AND
 2. it would be difficult or costly for plaintiff to counter the false advertising (advertising in question could be “cured with relative ease”)

Tortious Conduct

Misleading Tortious Conduct- Standard

- A monopolist's misleading and deceptive tortious conduct that is illegal at common law or under another regulatory scheme (*e.g.*, a little FTC Act) may be treated as “exclusionary” only when the conduct is institutional and pervasive and substantially harms the competitive process.
 - Institutional
 - Pervasive – measured in the context of the relevant geographic market
 - Impairs the competitive process
 - No rebuttable “de minimis” presumption – plaintiff's initial burden is to present a *prima facie* case of substantial harm to competition