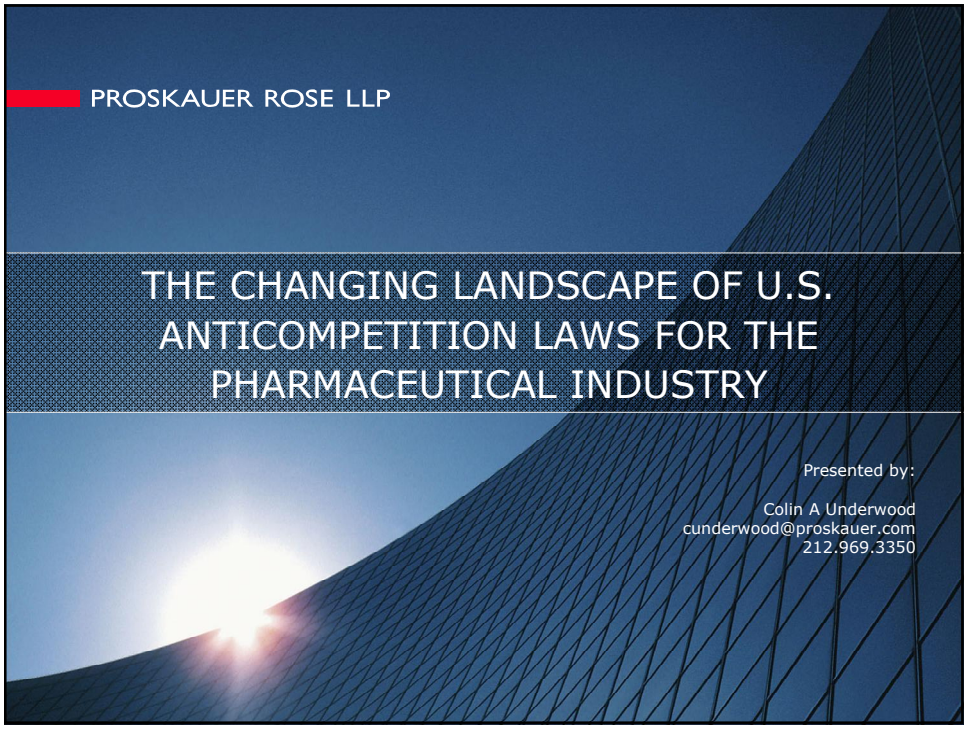



## Hatch-Waxman Act — The Basics

- Governs the procedure for approval and marketing of generic drugs.
- Under Hatch-Waxman, the marketing approval process for generic drug products is streamlined.
- Generic manufacturers may file an abbreviated New Drug Application (ANDA) that incorporates the safety/effectiveness data submitted by original pioneer drug manufacturer and adds only bioequivalence studies.
- Generic manufacturers may develop and test the product without fear of an infringement action by the patent holder.
- Paragraph IV provides a mechanism for the litigation of patent infringement disputes.

## Paragraph IV of the Hatch-Waxman Act

- Generic applicant asserts non-infringement or invalidity of patents
- Brand manufacturer can file suit for infringement upon receiving notice
- If filed, suit will delay marketing approval for 30 months
- If more than one generic files Paragraph IV, first to file can be eligible for 180-day market exclusivity




## Hatch-Waxman Act Today

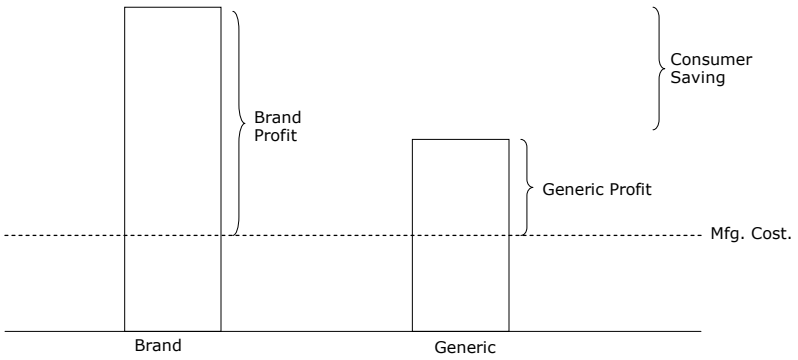
- Many top-selling prescription drugs in the US are currently the subject of patent challenges by generic firms seeking to enter market under the Hatch-Waxman Act:
  - **Singulair** — asthma/allergy drug
  - **Lovenox** — deep vein thrombosis / pulmonary embolism
  - **Abilify** — schizophrenia, bipolar, and depression drug

## "Reverse Payments" — The Theory

- In "most" patent litigation settlements, payment flows from *(accused) infringer* to *patentee*
- In "reverse payment" settlements, payment flows from *patentee* to *(accused) infringer*
  - alleged infringer agrees to delay developing or marketing product
  - Theory is invoked most commonly in context of generic pharmaceutical disputes, but not really limited to that context
  - **Incentive:** profit that generic anticipates << amount of profit brand-name company stands to lose




## "Reverse Payments" — The Theory (cont'd)



## Reasons to Oppose Reverse Payments

- **Opponents** of reverse payment settlements argue that permitting these settlements undermines the law's purpose:
  - "Hatch-Waxman was intended to give generic companies an incentive to challenge weak patents and to compete, not to take money in exchange for sitting on the sidelines." – FTC[1]
  - "The law has been turned on its head." - Representative Henry A. Waxman[2]
  - "Pay for delay" is the new phrasing

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1 *How Pay-for-Delay Settlements Make Consumers and the Federal Government Pay More for Much Needed Drugs: Hearing Before the H. Subcommittee on Commerce, Trade, and Consumer Protection of the Committee on Energy and Commerce* (March 31, 2009) (statement of Commissioner J. Thomas Rosch).

2 Cheryl Gay Stolberg et al., *Keeping Down the Competition; How Companies Stall Generics and Keep Themselves Healthy*, N.Y. TIMES , July 23, 2000, at A11 (quoting Rep. Waxman).




## "Reverse Payments" — Questions

- In "most" patent litigation settlements, payment flows from *infringer* to *patentee*
  - True? If so, does it reflect an underlying economic principle or perhaps unequal bargaining power
- Possible explanations:
  - Accused infringers are usually liable
  - Accused infringers usually have less bargaining power
- Is there a bias in considering only those cases that settle — will that shift the pattern of which party pays?
  - Both parties have incentive to avoid litigation costs, if outcome can be predicted
  - Patent owners might have more incentive to settle cases they are less certain of winning
- If the pattern is different in generic drug litigation, is that because of different economics or different bargaining positions?

## Reasons to Allow Reverse Payments

- **Supporters** of reverse payment settlements argue that legislation to ban reverse payment settlements is unwarranted:
  - Such settlements typically allow generic entry before patent expiration, benefiting consumers
  - "Impossible" to settle Hatch-Waxman patent cases without payments to the generic challenger
  - Barring payments to generic firms is simply putting a thumb on the scales
    - May reduce settlements / increase litigation costs
    - May mean fewer generic firms will undertake patent challenges




## Decisions on Reverse Payments

- Appellate court decisions permitting reverse payment settlements:
  - **2005**:
    - *Schering-Plough Corp. v. FTC*[3] – Eleventh Circuit reversed decision by the FTC that a substantial exclusion payment made to induce a generic drug company from entering the market before the expiration of the branded drug's patent was illegal
    - *In re Tamoxifen Citrate Antitrust Litig.*[4] – Second Circuit upheld the legality of a reverse payment settlement
    - Supreme Court denied certiorari in both cases

[3] 402 F.3d 1056 (11th Cir. 2005), cert. denied, 548 U.S. 919 (2006)

[4] 429 F.3d 370 (2d Cir. 2005), amended, 466 F.3d 187 (2d Cir. 2006), cert. denied, 127 S.Ct. 3001 (2007).

## Decisions on Reverse Payments (cont'd)

- Appellate court decisions permitting reverse payment settlements: (cont'd)
  - **2008:**
    - *In re Ciprofloxacin Hydrochloride Antitrust Litig.*[5] - Federal Circuit held that "absent fraud … or sham litigation," the mere presence of a patent entitles the patent holder to purchase protection from competition.
      - cert petition pending

[5] 544 F.3d 1323 (Fed. Cir. 2008), petition for cert. filed, __ U.S.L.W. __ (U.S. Mar. 23, 2009) (No. 08-1194)




## Decisions on Reverse Payments (cont'd)

- **The *Schering* case: The Settlement**
  - Upsher-Smith Laboratories (Upsher) and ESE Lederle, Inc (ELI) sought approval from FDA to market generic versions of Schering-Plough Corp.'s potassium chloride product.
  - Schering sued both Upsher and ELI for patent infringement.
  - Both cases settled:
    - Schering paid Upsher a total of $60 million to license five Upsher products and paid ELI $10 million dollars.
    - Upsher agreed to delay market entry of generic product.
    - ELI agreed to delay market entry of generic product into the market until three years prior to the expiration of the patent.

## Decisions on Reverse Payments (cont'd)

- **The *Schering* case (11th Circuit): Antitrust Decision**
  - FTC found settlements violated Section 1 of the Sherman Antitrust Act and Section 5 of the Federal Trade Commission Act.
  - FTC also found Schering monopolized and conspired to monopolize the potassium supplement market.
  - 11th Circuit reversed, held that monetary payments made to an alleged infringer as part of a patent litigation settlement did not constitute a per se violation of antitrust law:
    - In context of patent litigation, anticompetitive effect may be no more broad than the patent's own exclusionary power.
    - Settlement was within patent's exclusionary power, reflects a reasonable implementation of the protections afforded by patent law.




## Decisions on Reverse Payments (cont'd)

- **The *Schering* case (11th Circuit): Antitrust Decision (cont'd)**
  - Rejected FTC's assertion that reverse payments settlement agreements violate Sherman Act or FTC Act.
  - Reasoned that rules encouraging patent litigation could end up hindering innovation:
    - "[T]he caustic environment of patent litigation may actually decrease product innovation by amplifying the period of uncertainty around [an inventor's] ability to research, develop, and market the patented product or allegedly infringing product."
  - Found that a rule too liberal in allowing settlements was seen as preferable to litigation:
    - "The intensified guesswork involved with lengthy litigation cuts against the benefits proposed by a rule that forecloses a patentee's ability to settle its infringement claim."

## Decisions on Reverse Payments (cont'd)

- **The *Tamoxifen* case (2d Circuit): The Settlement**
  - Brand-name (Imperial Chemical Industries/Zeneca) obtained a patent in 1985 for the drug tamoxifen (used in the treatment of breast cancer).
  - Generic (Barr Industries) sought to produce a generic version.
  - Zeneca filed suit for patent infringement.
  - District court **found the patent invalid**.
  - Companies entered into settlement agreement:
    - Zeneca paid Barr $21 million and granted Barr a non-exclusive license to sell Brand-name manufactured tamoxifen.
    - Barr agreed not to market its own generic version of tamoxifen until patent expired or was invalidated by another party.




## Decisions on Reverse Payments (cont'd)

- **The *Tamoxifen* case (2d Circuit): Case Background (cont'd)**
  - Zeneca and Barr's successfully vacated district court's judgment that the patent was invalid.
  - Consumer groups file lawsuits challenging the settlement alleging restraint of trade in violation of the antitrust laws.
  - Defendants successfully move to dismiss action for failure to state a claim upon which relief could be granted.
  - On appeal, 2d Circuit concludes that a patent settlement involving a reverse payment is generally not a violation of the antitrust laws so long as the patent holder is not acting in **bad faith beyond the limits of the patent monopoly** to restrain or monopolize trade.

## Decisions on Reverse Payments (cont'd)

- **The *Tamoxifen* case (2d Circuit): Outcome**
  - Reverse payment settlement does not violate antitrust law "so long as the patent litigation is **neither a sham or otherwise baseless.**"
  - Dismissed the suggestion that an antitrust violation should be found where the amount of the reverse payment exceeds the profit the competitor could have earned had it continued to manufacture the accused product.
  - Even if a large reverse payment might betray patent owner's doubts regarding its ability to prevail on the merits in its case, those doubts do not mean that the litigation is a sham or baseless.
  - Because the settlement agreement did not extend the monopoly of the tamoxifen patent, there was no basis for refusing to allow reverse payments.




## Decisions on Reverse Payments (cont'd)

- **The *Cipro* case (Federal Circuit):**
  - Bayer settled patent litigation with manufacturer of generic counterpart (Barr):
    - Bayer agreed to make periodic payments to Barr ultimately totaling almost $400 million.
    - Barr agreed to delay marketing its generic version of Cipro for almost seven years.
  - The Federal Circuit Court of Appeals held that "**absent fraud** before the [Patent and Trademark Office] or **sham litigation**," the mere presence of a patent entitles the patent holder to purchase protection from competition.[6]
  - Plaintiffs have asked the Supreme Court to review the decision.

[6] 544 F.3d at 1336.

## Decisions on Reverse Payments (cont'd)

- **The *Cipro* case (Federal Circuit): (cont'd)**
- In seeking review by the Supreme Court, Petitioners point to the irreconcilable differences between the rules of the various Circuit Courts in deciding the issue of reverse payment agreements.
- Petitioners indicate that the decisions of Tamoxifen and Schering from the Second and Eleventh Circuits, respectively, account for the increase in reverse payment arrangements.
  - In 2004, of the 14 reported agreements between brand and generic manufacturers, none contained a reverse payment agreement.
  - In 2005, there were 16 settlements and 3 included reverse payment arrangements.




## Decisions on Reverse Payments (cont'd)

- **The *Cipro* case (Federal Circuit): (cont'd)**
  - In 2006 and 2007, the FTC discovered a dramatic increase in exclusion payments.
  - For fiscal year 2006, 14 out of 28 final settlements included reverse payment provisions and in 2007, 14 out of 33 settlement agreements included a reverse payment.
- Petitioners argue that the Cipro case is a straight-forward reverse payment arrangement, and thus is ideal for the Supreme Court to clarify the standard.

## Recent FTC Actions

- *FTC v. Cephalon, Inc.* (February 2008)
- *FTC v. Watson Pharmaceuticals* (January 2009)




## *FTC v. Cephalon, Inc.*[8]

- Cephalon, Inc.'s leading product is Provigil (a drug used to treat excessive sleepiness caused by narcolepsy and sleep apnea - annual sales of more than $800 million).
- FTC charges that Cephalon agreed to pay over $200 million collectively to settle patent litigation with four manufacturers of generic versions of Provigil to induce them to abandon their plans to sell generic Provigil for six years (until 2012).
  - Cephalon's CEO observed shortly after entering these agreements: "We were able to get six more years of patent protection. *That's $4 billion in sales that no one expected*."[9]

[8] *FTC v. Cephalon, Inc.*, No. 08-cv-2141 (E.D. Pa. complaint filed Feb. 13, 2008), *available at* http://www2.ftc.gov/os/caselist/0610182/080213complaint.pdf.

[9] John George, *Hurdles Ahead for Cephalon*, PHILADELPHIA BUSINESS JOURNAL, March 17, 2006 (quoting Cephalon CEO Frank Baldino) (emphasis added).

## *FTC v. Cephalon, Inc.* (cont'd)

- The court has yet to rule on Cephalon's motion to dismiss.
- Cephalon has instituted two price increases on Provigil since the Commission filed its complaint.




## *FTC v. Watson Pharmaceuticals*[10]

- Solvay Pharmaceuticals launched an extremely successful drug called **Androgel**. Watson and other companies filed Paragraph IV ANDAs, and Solvay sued for patent infringement.
- The parties settled with Solvay agreeing to pay the drug companies (including Watson) sizable amounts in exchange for their agreement to withhold from launching any generic brand of Androgel until 2015.
- FTC brought a complaint against Watson and other drug companies for "conspiring" to delay the sale of the generic version of Androgel until 2015.

[10] *FTC v. Watson Pharmaceuticals, Inc.*, No. 09-00598 (C.D. Cal. 25 first amended complaint filed Jan. 12, 2009), *available at* http://www2.ftc.gov/os/caselist/0710060/090212amendedcmpt.pdf.

## *FTC v. Watson* (cont'd)

- FTC Commissioner John Leibowitz (now Chairman) issued a separate concurring statement:
  - Advocates for the elimination of the "pay-for-delay" settlements and recites that in 2006-2007, 26 out of 61 brand-generic patent settlements include some type of payment to the generic and the generic's agreement to stay out of the market.
  - He states his support for two ways to eliminate these types of settlements: (i) continuing the challenges against patent settlements; and (ii) advocating for legislation which would ban payments from the brand to the generic.




## The FTC Faces Obstacles When it Challenges Reverse Payments

- The FTC recognizes that litigation challenges to reverse payment settlements may be ineffective in the current environment.
  - Litigation may often be stalled at district court level. (Example: *Provigil* case has been stalled for almost a year).
  - Outcome of litigation is uncertain under the *Schering, Tamoxifen*, and *Cipro* decisions.
  - Substantial cost to consumers, employers, and government programs.

# The FTC Stands Firmly

- **The FTC has strongly criticized these permissive reverse payment decisions:**
  - "These holdings disrupt the carefully balanced patent system by
    - overprotecting weak and narrow patents;
    - allowing patent holders to buy protection that their parents cannot provide; and
    - ignoring consumers' interests in competition safeguarded by the antitrust laws."[11]
  - *February 2009*: FTC announces that eliminating reverse payments is "one of the most important objectives for antitrust enforcement in America today."[12]

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11 *How Pay-for-Delay Settlements Make Consumers and the Federal Government Pay More for Much Needed Drugs: Hearing Before the H. Subcommittee on Commerce, Trade, and Consumer Protection of the Committee on Energy and Commerce* (March 31, 2009) (statement of Commissioner J. Thomas Rosch).

12 *F.T.C. v. Watson Pharmaceuticals*, Concurring Statement of Commissioner Jon Leibowitz (February 2009)




# FTC Concerns

- **Who does the FTC want to protect?**
  - Individual consumers
  - Federal and state governments
    - In 2008, the federal government was projected to have accounted for 31% of the $235 billion spent on prescription drugs.[13]
    - This share is expected to rise to 40% by 2018.
  - Businesses
    - Insurers
    - Retail pharmacies — significantly higher margin on lower-priced generics

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13 Centers for Medicare and Medicaid Services, Office of the 4 Actuary, Table 11, *Prescription Drug Expenditures; Aggregate and per Capita Amounts, Percent Distribution and Annual Percent Change by Source of Funds: Calendar Years 2003-2018* (2009), *available at* http://www.cms.hhs.gov/NationalHealthExpendData/downloads/proj2008.pdf.

# FTC's Concerns over Reverse Payments

1. The profitability of delaying generic entry means that these agreements will become more prevalent.
   - "In the current legal climate, there is every reason to expect the upsurge in such settlements to continue, and early entry of generics under Hatch-Waxman to decline."
   - Amount of money brand name will lose – profit generic anticipates = amount consumers would save.
     - Generic competition following successful patent challenges involving just four major brand-name drugs (Prozac, Zantac, Taxol, and Platinol) was estimated to have saved consumers more than $9 billion.[15]

[15] *Generic Pharmaceuticals Marketplace Access and Consumer Issues: Hearing Before the Senate Commerce Comm.*, 107th Cong. (Apr. 23, 2002) (statement of Kathleen D. Jaeger, President & CEO, Generic Pharmaceutical Ass'n) at 12, *available at* http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=107_senate_hearings&docid=f:90155.pdf.




# FTC's Concerns over Reverse Payments (cont'd)

2. **The 180-Day Exclusivity as a Bottleneck to Generic Entry:**
   - Hatch-Waxman Act's 180-day exclusivity period currently allows the potential for a settlement between a brand-name company and a first generic filer to generate a bottleneck that prevents any generic competition.
     - Act was designed to provide a mechanism for a later filer to eliminate this bottleneck by specifying that if the later filer can get a court ruling that it does not infringe, the first filer must "use or lose" its exclusivity period.
     - Under current law, the decision must be "a final decision from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the patent is invalid or not infringed."[16]
     - That decision acts as a forfeiture event that forces the first filer to either use or lose its exclusivity period within 75 days.

# FTC's Concerns over Reverse Payments (cont'd)

2. **The 180-Day Exclusivity as a Bottleneck to Generic Entry: (cont'd)**
   - Brand name companies have been able to use strategies to avoid the possibility that the generic company will obtain the favorable court decision it needs to relieve the bottleneck.
     - Danger that a brand company could use the 180-day exclusivity to block entry by
       - choosing not to sue a later filing generic and
       - avoiding a declaratory judgment action by that generic.
     - Section 4 of H.R. 1706 is designed to address that problem.




# FTC's Concerns over Reverse Payments (cont'd)

2. **The 180-Day Exclusivity as a Bottleneck to Generic Entry: (cont'd)**
   - Recent legal developments concerning the availability of declaratory judgment suits to later generics seeking to eliminate the 180-day bottleneck suggest that branded drug firms can no longer ensure that they will be able to avoid a declaratory judgment action merely by failing to sue the generic applicant or granting a covenant not to sue.
     - *Caraco Pharm. v. Forest Labs.*[17] – Federal Circuit found that the patentee's grant of a covenant not to sue did not eliminate the controversy between the parties (2008).

[17] 527 F.3d 1278 (Fed. Cir. 2008), cert denied, 77 U.S.L.W. 3308 (U.S. Feb. 23, 2009) (No. 08-624)

# FTC's Concerns over Reverse Payments (cont'd)

2. **The 180-Day Exclusivity as a Bottleneck to Generic Entry: (cont'd)**
   - *Ivax Pharm. v. AstraZeneca*,[18]; *Dr. Reddy's Labs. v. AstraZeneca*.- district court has read Caraco to apply only to pre-MMA ANDAs (2008).
   - Another district court has rejected that view and held that the Federal Circuit's *Caraco* decision applies equally to ANDAs filed after enactment of the MMA. *See Dey, L.P. v. Sepracor, Inc.*[19]

[18] No. 08-2165, 2008 WL 4056518 (D.N.J Aug. 28, 2008) and No. 08-2496, 2008 WL 4056533 (D.N.J. Aug 28, 2008).

[19] No. 08-2496, 2009 WL 230001 (D. Del. Jan 30, 2009).




# FTC's Concerns over Reverse Payments (cont'd)

2. **The 180-Day Exclusivity as a Bottleneck to Generic Entry: (cont'd)**
   - "It is important that there be a clear and practical mechanism available to subsequent generic filers to seek to relieve the bottleneck created by the 180-day exclusivity when the brand-name manufacturer and first generic applicant have settled their litigation without resolving the issues of validity or infringement or are involved in protracted litigation."[20]

[20] *How Pay-for-Delay Settlements Make Consumers and the Federal Government Pay More for Much Needed Drugs: Hearing Before the H. Subcommittee on Commerce, Trade, and Consumer Protection of the Committee on Energy and Commerce* (March 31, 2009) (statement of Commissioner J. Thomas Rosch).

# Medicare Prescription Drug, Improvement, and Modernization Act (MMA) (2003)

- Requires that brand name drug manufacturers and generic drug applicants file certain agreements with the FTC and the Assistant Attorney General.
- Agreements must be filed:
  - within 10 business days of execution of the agreement
  - prior to the date of the first commercial marketing of the generic drug that is the subject of the ANDA




# Medicare Prescription Drug, Improvement, and Modernization Act

***What Agreements Must be Filed?***

**1. Section 1112(a) Generic-Brand Agreements:**

- Section 1112(a) requires a generic drug applicant that has submitted an Abbreviated New Drug Application (ANDA) containing a certification under Section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act (FFDCA) and a brand name company that enter into an agreement regarding
  - the manufacture, marketing, or sale of a brand name drug that is listed in the ANDA involved;
  - the manufacture, marketing, or sale of the generic drug for which the ANDA was submitted; or
  - the 180-day period

# Medicare Prescription Drug Modernization Act

***What Agreements Must be Filed?***

**2. Section 1112(b) Generic-Generic Agreements:**

- Section 1112(b) requires a generic drug applicant that has submitted an ANDA containing a certification under Section 205(j)(2)(A)(vii)(IV) of the FFDCA with respect to a listed drug and another generic drug applicant that has submitted an ANDA containing such a certification for the same listed drug that enter into an agreement related to the 180-day period referred to in Section 505(j)(5)(B)(iv) of the FFDCA, to file the agreement with the Antitrust Agencies, subject to the requirements of Section 1112(c).




# Example of Action brought under the Medicare Prescription Drug Modernization Act: *FTC v. Bristol-Myers Squibb, Co*.

- As required by the MMA, Bristol-Myers Squibb, Co. ("BMS") submitted a proposed settlement agreement to the FTC and DOJ in an attempt to resolve a patent dispute with Apotex, Inc.
- The FTC discovered a questionable provision whereby BMS agreed to refrain from launching any generic version of Plavix for six months, while Apotex would be the exclusive seller.
- BMS submitted a revised agreement excluding the questionable provision, and subsequently certified that the settlement represented the entirety of the understandings between the parties. Apotex, however, admitted that BMS made oral representations.
- The DOJ and FTC began an investigation and found that BMS failed to disclose the oral representations.
  - BMS pled guilty to the DOJ's criminal charges for perjury and paid $1 million in criminal fines.
  - The FTC brought a civil suit and BMS was ordered to pay $2.1 million.

## Summary: Current state of the law

- Anticompetitive effects arising from a reverse payment agreement are likely to be considered lawfully within the scope of the patent's protection, unless:
  - the agreement prevents or restrains the introduction of unrelated or non-infringing products
  - the agreement creates a bottleneck on patent challenges, delays market entry by other generics or manipulates the 180-day exclusivity period granted to the first generic challenger
  - the patent was procured by fraud and is clearly invalid
  - the patent litigation is objectively baseless




## Recent Developments: Summary (cont'd)

- Opponents of reverse payments:
  - Members of Congress
    - Bills introduced in both the House and the Senate to address reverse payment settlements
  - Obama Administration
    - President Obama explained in his recent budget that "The Administration will prevent drug companies from blocking generic drugs from consumers by prohibiting anticompetitive agreements and collusion between brand name and generic drug manufacturers intended to keep generic drugs off the market."[21]

[21] OFFICE OF MGMT. & BUDGET , EXEC . OFFICE OF THE PRESIDENT, BUDGET OF THE UNITED STATES GOVERNMENT , FISCAL YEAR 2010 (2009) (proposed), at 28, available at http://www.whitehouse.gov/omb/assets/fy2010_new_era/A_New_Era_of_ Responsibility2.pdf.

# Recent Developments: Summary (cont'd)

- Department of Justice
  - Assistant Attorney General Christine Varney recently testified before the Senate Judiciary Committee that she supported opposition to "reverse payments" and would work to "align" the positions of the Department of Justice and the FTC.[22]

[22] Executive Nominations: Hearing Before the S. Judiciary Comm., 111th Cong. 38-39 (2009) (exchange between Sen. Herb Kohl, Member, S. Judiciary Comm., and Christine Anne Varney, Nominee, Assistant Att'y Gen., Antitrust Division, Department of Justice).




# Recent developments: Legislation

- **Bills introduced in both the House and Senate:**
  - "The Preserve Access to Affordable Generics Act" (S. 369, 111th Cong. 2009)
  - March 25, 2009: "Protecting Consumer Access to Generic Drugs Act of 2009" (H.R. 1706)

## Protecting Consumer Access to Generic Drugs Act of 2009 (H.R. 1706):

- **Conduct Prohibited:**
  - Makes it unlawful for any person to directly or indirectly be a party to any agreement resolving or settling a patent infringement claim in which
    - an ANDA filer receives **anything of value**; and
    - the ANDA filer agrees not to research, develop, manufacture, market, or sell, for any period of time, the drug that is to be manufactured under the ANDA involved and is the subject of the patent infringement claim.




## Protecting Consumer Access to Generic Drugs Act of 2009 (H.R. 1706): (cont'd)

- **Exceptions:**
  - Does not prohibit a resolution or settlement of a patent infringement claim in which the value received by the ANDA filer includes no more than:
    - the right to market the drug that is to be manufactured under the ANDA involved and is the subject of the patent infringement claim, before the expiration of
      - the patent that is the basis for the patent infringement claim; or
      - any other statutory exclusivity that would prevent the marketing of such drug; and
    - the waiver of a patent infringement claim for damages based on prior marketing of such drug

## Protecting Consumer Access to Generic Drugs Act of 2009 (H.R. 1706): (cont'd)

- **Enforcement:**
  - A violation of subsection (a) shall be treated as an unfair and deceptive act or practice and an unfair method of competition in or affecting interstate commerce prohibited under Section 5 of the Federal Trade Commission Act (15 U.S.C. § 45). The Federal Trade Commission shall enforce this Act in the same manner, by the same means, and with the same jurisdiction as though all applicable terms and provisions of the Federal Trade Commission Act were incorporated into and made a part of this Act.




## Protecting Consumer Access to Generic Drugs Act of 2009 (H.R. 1706): (cont'd)

- **SEC. 3. FTC Rulemaking.**
  - "The Federal Trade Commission may . . . exempt certain agreements described in section 2 if the Commission finds such agreements to be in furtherance of market competition and for the benefit of consumers."
  - Such rules could include interpretive rules and general statements of policy with respect to the practices prohibited under Section 2 of the Sherman Act (Unilateral Conduct/Monopolization).

## Reverse Payment Legislation

- **The FTC is seeking legislative action, supporting H.R. 1706:**
  - "Legislative action concerning pay-for-delay settlements can be tailored to the special circumstances of pharmaceutical patent settlements and help to ensure that this unique framework works as Congress intends."
    - *How Pay-for-Delay Settlements Make Consumers and the Federal Government Pay More for Much Needed Drugs: Hearing Before the H. Subcommittee on Commerce, Trade, and Consumer Protection of the Committee on Energy and Commerce* (March 31, 2009) (statement of Commissioner J. Thomas Rosch).




## Previously, the DOJ has Disagreed with the FTC's Position

- **Justice Department has disagreed with the FTC regarding reverse payments:**
  - "This case… does not present an appropriate opportunity for this Court to determine the proper standards for distinguishing legitimate patent settlements, which further the important goals of encouraging innovation and minimizing unnecessary litigation, from illegitimate settlements that impermissibly restrain trade in violation of the antitrust laws."
    - Department of Justice *amicus curiae* filing in *Schering-Plough Corp.* (2005)

## Recent Developments at the DOJ: The Newly Installed Chief Antitrust Enforcer at the DOJ is Concerned about Reverse Payments

- Assistant Attorney General Varney has suggested that she might oppose drug patent settlements that include reverse payments.
  - Senator Specter asked Varney a series of questions concerning reverse payments and followed up with a letter requesting "more adequate answers."
  - Ms. Varney responded to Senator Specter with a March 25, 2009 letter
  - Excerpts:
    - "Every case must be examined on its own merits, and certainly there are some disputes where settlements can be procompetitive."
    - "A patent holder who enters into a commercial arrangement to allow a competitor to enter the market prior to the patent's expiration would most likely be procompetitive."




## Recent Developments at the DOJ (cont'd)

- Excerpts from AAG Varney (cont'd)
  - "The merits of any infringement claim can be difficult to determine. . . . [A]ntitrust authorities may have an interest in participating in instances where there is a settlement in cases when the underlying infringement claim is not resolved through a full adjudication."
  - "I continue to be concerned that certain reverse payment settlements, which slow the entry of generics drugs into the market, can negatively impact consumer choices and costs. . . . I think it is important for the antitrust agencies views are aligned on these issues, if possible. . . . I pledge to work with the FTC to align the agencies' views on this matter and develop a unified approach to dealing with reverse payment settlements."

## What to Expect from the DOJ Under Varney's Leadership

- Policy shift to more aggressive antitrust enforcement
  - Ms. Varney's first public remarks included an announcement that the DOJ will withdraw its Section 2 Unilateral Conduct Report
- Greater synchronization between the DOJ and FTC
- Support for legislation outlawing reverse payments.




## What to Expect: Conclusion

Through legislation, litigation or both, reverse payment settlements will be challenged.

[WATCH THIS SPACE]