Antitrust

FTC v. Qualcomm and Other Recent Antitrust Developments in High Tech & Life Sciences

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FTC v. Qualcomm

More SEP Developments

Life Sciences & Antitrust

Standard Development Organizations (SDOs)

- Establish specifications to ensure products from different sources are compatible.
- **Horizontal and vertical collusion** between competitors benefits consumers due to **interoperability**, **lower product costs**, and **increased price competition**.

Standards Essential Patents (SEPs)

- **SEPs claim technology that is:**
  - **incorporated** into a standard **and**
  - **necessary** to comply with the standard
- **Contrast "implementation" patents on:**
  - a standard's "optional" features, or
  - non-standardized device features

FRAND Obligations

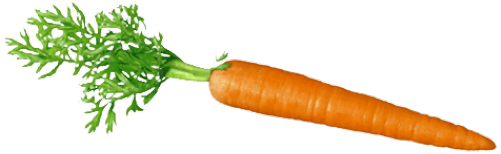
- SEP holders may have **"disproportionate market power"**
- SDOs often require contributors to:
  - **disclose** SEPs
  - commit to license SEPs on **fair, reasonable, and non-discriminatory** ("**FRAND**") terms
- Helps prevent:
  - patent "**hold up**" power
  - a monopoly on standard-complaint products

FTC v. Qualcomm: Technology at Issue

- Mobile devices use **modem chips** to communicate with cellular network.
  - Chips comply with telecom **standards** (3G, 4G LTE, 5G)
  - **Qualcomm**:
    - **Contributes** to standards
    - **Supplies** modem chips
    - **Licenses** SEPs and non-SEPs with claims on chips, phones, and features

District Court's Primary Findings on Qualcomm Anticompetitive Conduct

- **Sticks**
  - **Refused to license modem chips "exhaustively"**
  - "**No license, no chips**"
  - **"Unreasonable" device royalty** acted as a "surcharge" on competitor chips
  - No claim charts or patent lists
  - Required royalty-free cross licenses



- **Carrots**
  - **Incentive funds** & rebates
  - Paid to extinguish antitrust claims

District Court "Found" Anticompetitive Effects

- **Refusing to license SEPs at the chip level**
  - Promoted rivals' exit from the market, prevented or delayed their entry, and hampered their success
  - Also a **FRAND violation**

What is "Non-discriminatory"?

- **Ninth Circuit precedent requires licensing "all comers"**

> **"SSOs requir[e] members who hold IP rights in standard-essential patents to agree to license those patents to all comers on terms that are 'reasonable and nondiscriminatory, or 'RAND.'"**

-*Microsoft Corp. v. Motorola, Inc.*, 696 F.3d 872, 875 (9th Cir. 2012)

What is "Non-discriminatory"?

- **Judge Koh found a contractual obligation to license component suppliers**

> **"Those binding precedents are clear: a SEP holder that commits to license its SEPs on FRAND terms must license those SEPs to all applicants."**

-*FTC v. Qualcomm*, 2018 WL 5848999 (N.D. Cal. Nov. 6, 2018)

But Wait, There's More!

- **"Qualcomm has an antitrust duty to license its SEPs to rival modem chip suppliers"**
  - A company usually has a right to "exercise [its] own independent discretion as to the parties with whom [it] will deal."
  - **Three factors "significant for antitrust liability"**

    (1) "unilateral termination of a voluntary and profitable course of dealing."

    (2) refusal to deal, even at retail price

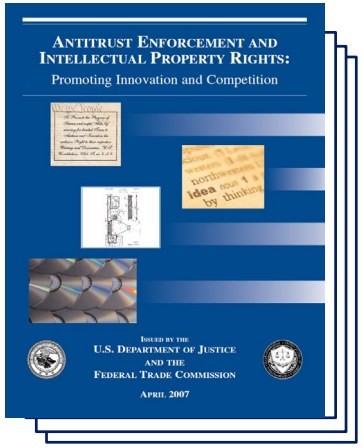
    (3) refusal to provide competitor a product already sold in retail market to others

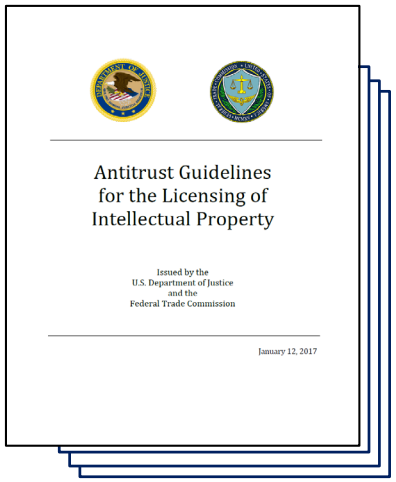
Patent Act Not Addressed

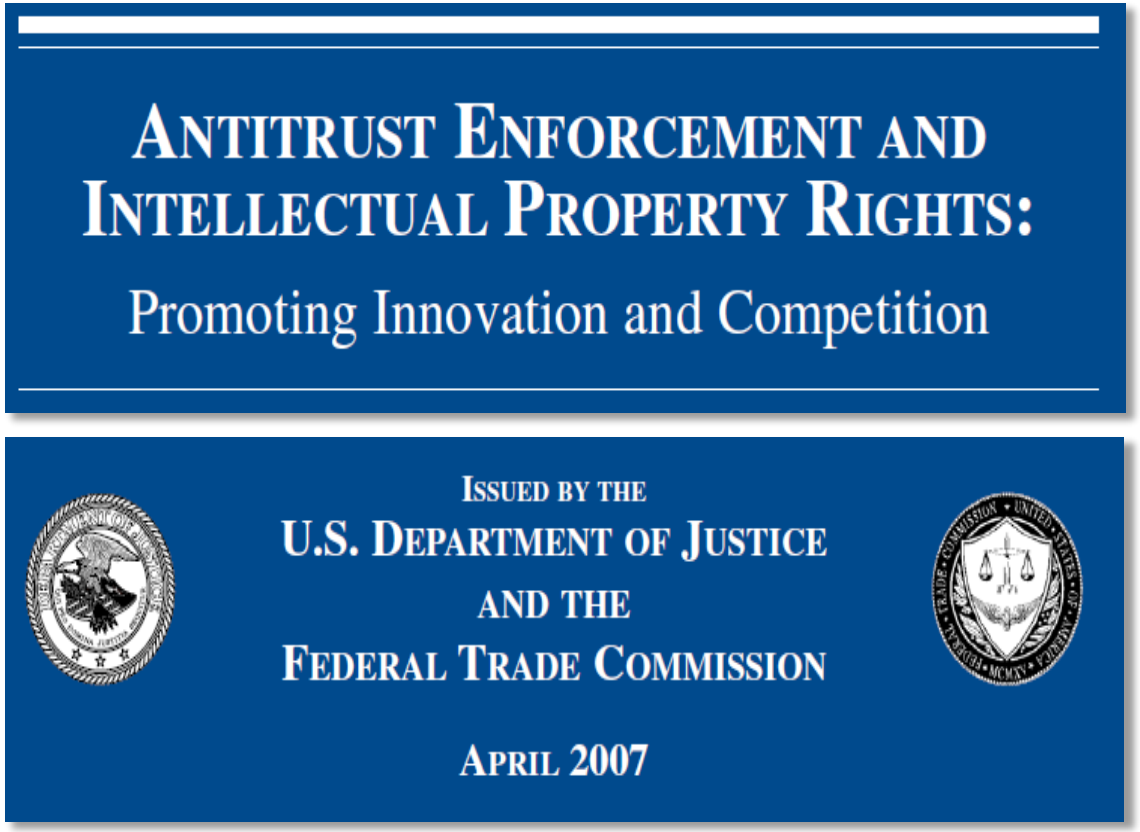
"No patent owner … shall be … deemed guilty of misuse or illegal extension of the patent right by reason of his having … refused to license or use any rights to the patent"

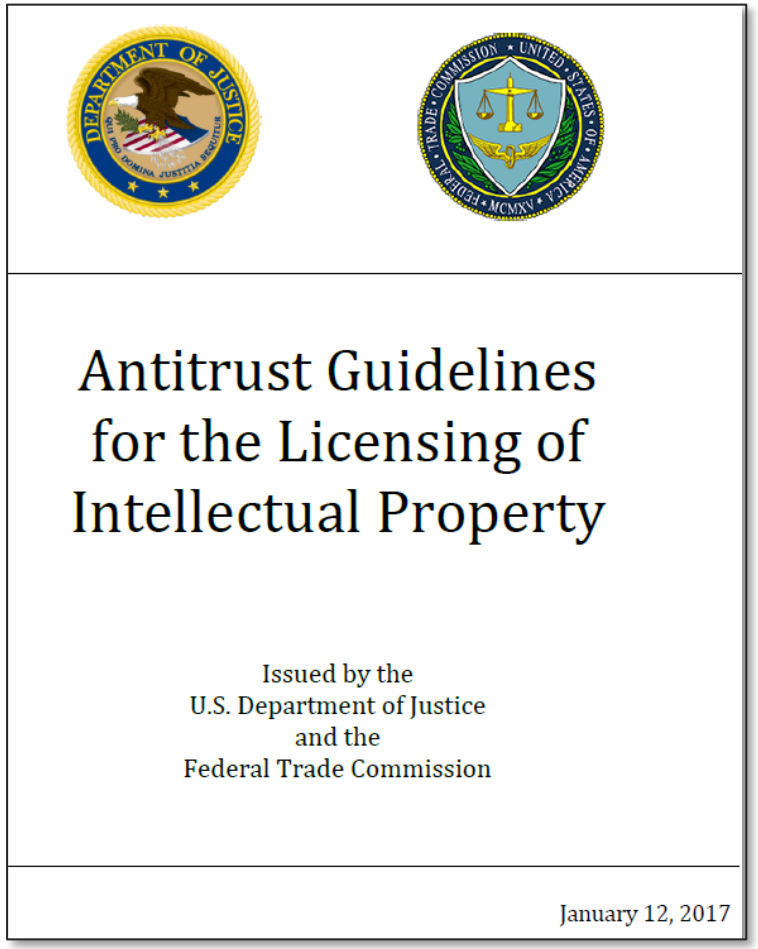
-35 USC Section 271(d)(4)

They used to be friends!









Department of Justice Developments

- **Indicated it will not pursue antitrust claims based on FRAND violations**
  - Focus on "**hold out**," rather than "**hold up**"
  - Skeptical of SDOs that shift bargaining leverage from IP creators to implementers, or vice versa.
  - Withdrew or revised support for prior biz review and policy letters
- **Business Review Letter *In re GSMA***

Remedy: Injunction and Reporting

(1) **End "No License, No Chips" policy** and renegotiate past licenses

(2) **Offer exhaustive FRAND licenses to chip suppliers** for SEPs

(3) **No exclusive deals** with OEMs for chip supply

(4) No interference with government investigations

(5) Report compliance to FTC annually for 7 years

FTC v. Qualcomm Status

- 9th Circuit Stayed the injunction
- Qualcomm reply due shortly
- Oral hearing: 2/13/2020
- Many Amicus Briefs, Statements of Interest, and Views on the opinion, the injunction, or both

How do you feel about the opinion/injunction?

- Cause of Action Institute
- Alliance of US Startups and Inventors for Jobs (USIJ)
- International Center for Law & Economics and Scholars of Law & Economics.
- Antitrust and Patent Law Professors, Economics, Scholars

- **FTC Commissioner Wilson (Op Ed)**
- **Department of Justice (DOJ)**
- Judge Michel

- Dolby
- Interdigital
- Nokia

- Open Markets Institute
- American Antitrust Institute & Public Knowledge
- R Street Institute
- Law & Economics Scholars
- Prof. Jorge Contreras
- Prof. Timothy Muris

- Fair Standards Alliance (Cisco, HP, Apple, …)
- High Tech Inventors Alliance (Amazon, Microsoft, …)
- Computer & Communications Industry Association (Facebook, Google, Samsung, …)
- ACT | The App Association
- **Association of Global Automakers & Alliance of Automobile Manufacturers**

- Intel
- MediaTek
- Continental Automotive and Denso

FTC v. Qualcomm

More SEP Developments

Life Sciences & Antitrust

Meanwhile, across the pond

- **Worldwide FRAND Rate Setting**
  - Appeal in *Unwired Planet v Huawei; Conversant v Huawei, ZTE*
  - UK injunction unless Huawei pays **global** FRAND rates set by UK
  - Only ~1% of Huawei's sales are in UK, 75%+ in China
  - **Many tensions**: (patent territoriality, global portfolios, international supply chains, comity & diplomacy, trade policy)
- **Anti³-Suit Injunctions³**
  - Nokia and Sharp (Avanci) v. Daimler & Continental
  - The new "Italian Torpedo"?

More SEP Developments

- **Anticompetitive Patent Aggregation Claims**
  - *Intel & Apple v. Fortress, Uniloc, VLSI, et al.* (N.D. Cal.)
  - *Capital One v. Intellectual Ventures, et al.* (Fed. Cir.)
- ***TCL v. Ericsson* Vacated & Reversed**
  - CDCA (Selna) awarded past and future royalties at FRAND rate
  - Ericsson **entitled to jury trial for past FRAND damages**
  - Vacated Judge Selna's top-down FRAND determination
- ***China - Nanjing Court (Conversant v. Huawei)***
  - Adopted **top-down FRAND methodology**
  - 4G rates potentially much lower than UK court's global rates

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Pharma – Hard Facts Cause Tough Problems

- Regardless of cause or reason, the fact that drug prices in the U.S. are generally higher than in other countries, and higher than in the past, is causing scrutiny of the pharma industry.
- In July 2019, it was reported a typical vial of insulin that will last a diabetic about 10 days costs about $300 without insurance in the United States. In Canada, the exact same type of insulin can be purchased for just $30.
- This has added impetus for increased antitrust scrutiny and new reporting requirements for pharma patent transactions.
- It has also contributed toward proposed legislation to promote generic development.

Hot Topics

- Reverse payment settlements evaluated based on consideration that changes hands, not just cash.
- Scrutiny of product hopping: When a drug maker discontinues a drug where patent is expiring and moves market to a new formulation of the drug that still has patent protection.
- Patent Thicket.
- Standards and Pharma

What Makes Pharma Antitrust Different?

- Because these cases and issues focus on settlements or licenses that follow patent litigation, and not out of the litigation itself, the law has been developed by the regional court of appeals, not the Federal Circuit.
- The net result is these cases seem to be focused on correcting the market issues for consumers of the drug, not protecting the patent owner's rights or the accused infringer's rights.

Reverse Payment Settlements

- *FTC v. Actavis*, 570 U.S. 136 (2013) resolved a circuit split over whether a "reverse settlement" "within the scope of the patent" was immune from antitrust scrutiny.
- Reverse settlements came about to take advantage of the Hatch-Waxman Act's abbreviated structure for generic approval--stay of FDA approval for first 30 months of litigation, and 180-day exclusivity period for the first ANDA filer.
- Before *Actavis*, these settlements were considered lawful as they did no more than preserve the scope of a monopoly of a presumptively valid patent that covers the drug, so long as they did not manipulate the Hatch-Waxman Act's provisions or employ other devices to extend the patent's life or scope.
- *Actavis* eliminated the patent immunity for reverse settlements.

Actavis's Rule of Reason Analysis

"The [Actavis] Court held that reverse payment settlements are to be analyzed under traditional rule of reason analysis. Id. [570 U.S. at 158-59]. Whether a reverse payment is anticompetitive "**depends upon its size, its scale in relation to the payor's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification.**" Id. at 159. The Court "le[ft] to the lower courts the structuring of the present rule-of-reason antitrust litigation," keeping in mind that the "basic question" in each case is whether a given reverse payment settlement agreement "unreasonably diminish[ed] competition in violation of the antitrust laws." Id. at 160, 141.

In the Matter of Impax Laboratories, No. 9373 at 6 (FTC March 28, 2019), appeal to 5th Circuit pending.

Reverse Payment Settlement

- Actavis involved over $300 million in "reverse payments," but the patent was never declared invalid, unenforceable or not infringed.
- *Noerr-Pennington*/First Amendment protection for patenting and enforcement requires proof of objective and subjective knowledge that the patent is either not infringed, unenforceable or invalid.
- *Actavis* does not look at the patent, only at the settlement: ***Assumes*** the patent owner knows its enforcement exceeds its legitimate rights due to large cash payment from plaintiff drug maker to the infringer.
- What about *Professional Real Estate Investors*???

The "No Authorized Generic" Play

- The generic that first files an ANDA is entitled to 180 days on the market to the exclusion of other generics.
  - This is "the generic" that "draws" the drug company's infringement suit, and precipitates the first challenge to the patents on the drug.
  - The exclusivity period is the challenger's reward for opening up the market.
  - But the drug company can come out with its own "authorized generic" during this 180 day period, undermining the generic's reward.
  - The promise by the drug maker not to introduce an authorized generic during the 180 day period is extremely valuable in both realizing profits and establishing market position with the industry.
  - And the extension of the original drug's exclusivity can permit the drug maker to come out with a new modified drug to try to "move" users of the same active ingredient to a new patent term: E.g., time-release, coating to ease digestion, film instead of tablets, etc.

In re Impax – FTC's First Application of *Actavis*

- FTC's first Commission decision applying *Actavis*, issued on March 29, 2019, the decision is now on appeal to the U.S. Fifth Circuit.
- In a reverse settlement that extended Endo's exclusivity period, Endo made a deal to give Impax the 180-day exclusive generic position on its drug by promising it would not introduce an "authorized generic" during the 180 day period, a contingent payment up to $102 million, and up to $40 million for an independent development and co-promotion deal.
- Endo needed nearly a year to introduce and move patients to a new version of the drug, which would not have been possible if a cheaper generic was on the market.
- The only guaranteed money was the $10 million minimum on the development and promotion deal.
- The real value in the deal was the 180-day exclusive generic position.

Actavis – Rule of Reason Applies

- *Actavis* held that a reverse payment settlement must be analyzed under the rule of reason because there can be legitimate reasons for such a deal: E.g., litigation cost savings, payment for services the infringer might perform (development, manufacturing, distribution).
- In *Impax*, at face value, the promised consideration was a minimum of $10 million for development and co-promotion of product, and a no "AG" deal.
- However, the contingent payment showed the value of the no "AG" deal was worth $102 million.
- In effect, Endo was paying *Impax* $112-$152 million to buy it time to develop a new variation of the drug and migrate patients to it – thereby extending Endo's patent rights.
- The value of the "non-cash" deal could be measured and compared to the value of the consideration given by the infringer…

California Reverse Payment Prohibition

- Bill AB 824 signed into law on October 7, 2019, now in Sections 13,400-13402 California Health and Safety Code.
- Makes reverse payment patent settlements presumptively illegal under the California Cartwright Act and Unfair Trade Practices Laws.

“Product Hopping”

- Hard Switch / Soft Switch
- *FTC v Reckitt Benckiser Group PLC*
- Proposed Legislation

Drugs, Medical Devices and Standard-Setting

- Standard-setting for interoperability and product safety/efficacy raise IP and antitrust issues.
- These issues have been seen in telecom, computer, DRAM and other systems, involving patent disclosures and FRAND licensing.
- These issues are now being seen in pharma in standardization of testing, *Momenta v. Amphastar*, 298 F.Supp.3d 258 (D. Mass. 2018), certification protocols for generic drugs in multi-competitor products, in which penalty or treatment for failure to disclose a patent to the standards group is being litigated. (This case settled, consumer class action pending trial.)
- Pharma is not up on the law on patent disclosures and FRAND, but these issues are now coming…

"Patent Thicket"

- *Abbvie v Boeringer Ingelheim*: "unclean hands"
- *Local 1500 v. AbbVie*: Section 2 monopolization
- Proposed Legislation

Reporting Requirements

- Frustration over pharma prices has drawn criticism over patent transactions.
- Failing agreement on how to deal with these issues in substance, Congress and states are looking to add more process.
- October 10, 2018, new reporting requirement for patent licenses was established in Patients' Right to Know Act, SB 2554, Section 1112 of the MEDICARE PRESCRIPTION DRUG, IMPROVEMENT AND MODERNIZATION ACT OF 2003 (as amended). 21 USC § 355, 1112(a)
  - Requires reporting of certain settlements between patented and generic drugs and biologics.
  - Requires reporting of licenses that provide some type of exclusivity without regard to valuation.
  - Exclusivity, however, is when control is given over any formulation or therapeutic use.
    - Co-development may be exclusivity is licensee controls it.
    - Licensor as contract manufacturer for licensee may be exclusivity.

Pharma and High Tech Antitrust Theories Mix

- Do economics of different markets facilitate or eliminate convergence of theories popular in Pharma with those in High-Tech?
- Patent thicket allegations in *Local 1500 v AbbVie* include some cross-over with allegations against Xerox's copy patent aggregation. *SCM v. Xerox*, 645 F.2d 1195 (2nd Cir. 1981).
- *Actavis*-type claims have overcome initial motion practice in at least one high tech case now pending.
- Standard-setting law developed in High-Tech is now relevant to standards being developed for drug testing protocols and robotics used in patient treatment.

Thank You!

Qualcomm Patents

- 140,000 patents and pending apps in 3 categories:
  - (1) cellular SEPs
  - (2) non-cellular SEPs
  - (3) non-SEP "implementation patents"
- Primarily uses portfolio licenses that include all 3 categories
- Typically licenses at the "handset" level, not the chips

The FTC and Sherman Acts

The FTC Act prohibits "[u]nfair methods of competition," which include violations of the Sherman Act.

The Sherman Act, Section 1

- **Prohibits contracts, combinations, conspiracies, in restraint of trade.**
- **Must prove:**
  - **(1) the existence of an agreement, and**
  - **(2) that the agreement was an unreasonable restraint of trade.**
- **Need not establish monopoly control if defendant plays "enough of a role in the market to impair competition significantly"**

Section 1, Rule of Reason Analysis

(1) Plaintiff's initial burden to show the restraint has a substantial anticompetitive effect that harms consumers

(2) Burden shifts to defendant to show a procompetitive rationale

(3) Burden shifts back to the plaintiff to show procompetitive efficiencies could be reasonably achieved through less anticompetitive means.

The Sherman Act, Section 2

- Unlawful for a firm to "monopolize" through:
  - (1) possession of monopoly power in the relevant market and
  - (2) willful acquisition or maintenance of that power through exclusionary conduct as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident
- Must have "anticompetitive effect" by harming the competitive process and thereby harming consumers

Prior QCOM Antitrust Rulings

- **EU preliminary finding of predatory pricing (2015)**
- **China's "rectification plan" (2015)**
  - **Requires QCOM to offer SEP-only licenses to China patents at specified rates.**
  - **QCOM avoided more aggressive rate cuts by making $150M contribution to Chinese govt. (R%D investment fund)**

Prior QCOM Antitrust Rulings

- **Japan FTC (9/2009)**
  - **Japanese licensees were improperly forced to cross-license patents to QCOM on a royalty-free basis and to accept a non-assert provision**
  - **Issued cease and desist order; stayed pending administrative hearings**

Prior QCOM Antitrust Rulings

- **Korean FTC (1/2010 and 1/2017)**
  - **Found QCOM's practices violated Korean Law:**
    - **(1) refusing to license SEPs to component suppliers**
    - **(2) "No License, No Chips" policy**
    - **(3) "coercing agreement terms"**
  - **Imposed $927M fine**

Prior QCOM Antitrust Rulings

- **Taiwan FTC (2017)**
  - **QCOM violated Taiwan law by:**
    - **(1) refusing to license modem chip rivals,**
    - **(2) refusing to supply modem chips to OEMs who are unlicensed, and**
    - **(3) providing discounts to Apple in exchange for exclusivity.**
  - **Imposed $778M fine**

District Court Found Royalty Rates "Unreasonably High"

- **Royalty rate analysis:**
  - QCOM's contributions to standards did not justify its rates. SEP share declined and patents expired, but **rates stayed the same for 30 years** (5% of handset price)
  - **Rates were applied to handsets**, but modems do not drive handset value in modern devices
  - Handset as royalty base violates Federal Circuit "apportionment" law
  - Rates never tested in litigation
  - **Refused to give patent lists or patent claim charts** during patent license negotiations
- **Modem chip market share and "no license, no chips" policy sustained "unreasonably high" rates**

Product-Hopping to Extend Exclusivity

- Product-hopping is when the drug maker tries to preserve its monopoly over a successful drug by making a new drug that is not pharmaceutically equivalent to the prior drug and then discontinuing the original drug or limiting its production. For example, reformulating the a tablet into a film and then discontinuing the tablet.
- ANDA requires that a generic be pharmaceutically equivalent for a generic to take advantage of abbreviated FDA approval.
- States have laws that either permit or require substitution of pharmaceutically equivalent generic drugs for the brand name. But if the original drug is EOL, then there is no generic to substitute for the brand name.
- In *Impax*, the plan was to reformulate the drug into a non-crushable version and migrate patients to the new formulation. Endo needed several months to complete this process and migrate patients. The reverse payment to Impax was designed to "buy time."

Product-Hopping? Bad for Patents?

- If the modification to a drug is a patentable improvement over the prior drug and the FDA approves it, can the selling of it be an antitrust violation?
- Can a drug maker who presses the original drug EOL be penalized for not selling the former product?
- Does the drug maker who disparages its discontinued product as unsafe compared to its new product engage in subterfuge that is anticompetitive?
- Evolving case law has shown factual differences result in different results, with subterfuge and deliberate wrongdoing crossing any line.

Patent Thicket -- *Local 1500 v. AbbVie*

- Class action lawsuit on behalf of purchasers of humira, AbbVie's highly successful product.
- AbbVie has 100 or more patents on humira, a "patent thicket".
- Seven generic manufacturers settled litigation whereby the got licenses to European markets and one year early entry into the US.
- Class alleges this is a conspiracy to allocate markets and to perpetuate the AbbVie-humira monopoly.
- Filed March 2019 by class.
- AbbVie's motion to dismiss filed in October 2019, pending, no ruling on the merits of the allegations as of now.