Product Improvements and Life Cycle Management – Antitrust Pitfalls

NJ IP Law Association's 26th Annual Pharmaceutical/Chemical Patent Practice Update

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December 5, 2012

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Product Improvements and Life Cycle Management – Antitrust Pitfalls

- **Agenda**
  - Commercial strategies for extending product life.
    - State drug product selection (DPS) laws.
  - Product switching strategies – antitrust cases.
    - *Abbott Labs v. Teva Pharm.*
    - *Walgreen Co. v. AstraZeneca.*
  - Settlements of product switching cases.
    - FTC actions.
    - K-Dur.
    - Supreme Court review?

Product Improvements and Life Cycle Management – Antitrust Pitfalls

- **Problem: How to extend the life of an existing approved branded drug facing patent expiration.**

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Commercial Strategies for Extending Product Life

- **Problem: How to extend the life of an existing approved branded drug facing patent expiration.**

- **Common strategy: Reformulation.**
  - Dosage type (*e.g.*, capsules, tablets, solutions).
  - Chemical changes.
  - Combination formulation with other drugs.

- **Market change by promoting reformulation.**

State Drug Product Selection (DPS) Laws

- **DPS laws**
  - Typically permit physicians to substitute AB-rated generic for brand-name drug.
  - Example: N.J.S.A. 24:6E-1 *et seq.*
    - Physician can specify brand-name drug.

- **Reformulated drug.**
  - No AB-rated generic.
  - Reformulated drug promoted by brand firm to switch market prior to generic entry.

Product Improvements and Life Cycle Management – Antitrust Pitfalls

Antitrust cases addressing product switching

Product Switching – Antitrust Cases

- ***Abbott Labs. v. Teva Pharm. USA, Inc.*, 432 F. Supp. 2d 408 (D. Del. 2006).**
  - TriCor aproved by FDA for capsule form.
  - Generic ANDA filing; Abbott files suit, receives stay.
  - Obtains FDA approval of new tablet during stay.
  - Stopped capsule sales & buys unsold inventory.
  - Changed capsule code in National Drug Data File (NDDF) to obsolete.
  - Second wave of ANDA suits for tablet; second stay.
  - Tablet reformulated – new dosage.
  - Stopped selling old tablets; NDDF code changed to obsolete.

Product Switching – Antitrust Cases

- **Held:**
  - Abbott's Motion to dismiss denied.
  - Prevented a choice between products “by removing the old formulations from the market while introducing new formulations.” (*Abbott*, 432 F. Supp. 2d at 422).
  - Rule-of-reason approach applied.
    - Look to consumer choice.
  - FDA's approval of label changes for new indications is not conclusive evidence of product improvement.

Product Switching – Antitrust Cases

- ***Walgreen Co. v. AstraZeneca Pharms.*, 534 F. Supp. 2d 146 (D.D.C. 2008).**
  - AZ's Prilosec (heartburn treatment) approved by FDA.
  - AZ's follow-on product (Nexium) approved eight months before Prilosec patents expired and generic entry.
  - Prilosec remained on market, NDDF codes unchanged
  - Generics allege violation of Sherman Act:
    - Exclusionary conduct in market shift from Prilosec to Nexium.
    - No medical reason for switching from Prilosec to Nexium.

Product Switching – Antitrust Cases

- **Held:**
  - AZ's motion to dismiss granted.
  - "The fact that a new product siphoned off some of the sales from the old product, and, in turn, depressed sales of the generic substitutes for the old product, does not create an antitrust cause of action . . ." (*Walgreen*, 534 F. Supp. 2d at 152).
  - Consumer choice is critical.
    - Introduction of Nexium increased consumer choice.
    - Prilosec remained in the market - competition between Prilosec and Nexium.
  - No exclusionary practice.
    - Nexium was under patent protection.
    - Enjoying benefit of patent protection is not exclusionary.

Product Switching – Antitrust Cases

- **What about Marketing efforts?**
  - Product switching through sales persuasion did not violate antitrust laws.
    - No finding of misrepresentation or fraud.
    - Marketing directed to physicians (Nexium only available by prescription).
    - Physicians are knowledgeable abut the subject matter.
  - Reduction in Prilosec sales and depression of Prilosec market by introduction of Nexium is ok.

Product Switching: Strategies

- **Consumer choice.**
  - Market shift from old product to follow-on product should be driven by consumer choice.
    - Avoid consumer coercion.
    - Maintain old product in the market while introducing follow-on product.
    - FDA regulates drug safety and efficacy, not competition between generics and brand drugs.
- **Marketing new product to physicians is not a misrepresentation.**
- **Demonstrate improvement of follow-on product.**

Product Improvements and Life Cycle Management – Antitrust Pitfalls

Product Switching:

Patent Settlements

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Product Switching: Patent Settlements

- **Payment by brand firm to first-filer ("paragraph IV" filer).**
  - "Pay-for-Delay."
    - Delay generic entry into the market by first-filer until a certain date.
    - Delay entry of subsequent generic filers.
  - "Reverse settlements."
    - Blocks challenges to brand firm's patent(s).
    - First-filer generic receives share of brand firm's profits.

Product Switching: Patent Settlements

- **Potential antitrust issues:**
  - Valid/Infringed Patent.
    - Rely on patent to restrict competition.
    - Reverse settlement increases competition.
  - Invalid/Non-infringed Patent.
    - Market Division.
    - Reverse settlement restricts competition between parties.

Product Switching: Patent Settlements

- ***FTC v. Warner Chilcott Holdings Co.***
  - Warner planned to introduce follow-on chewable Ovcon (oral contraceptive) before generic entry.
  - Product switch was not ready at generic entry.
  - Warner entered agreement with Barr to delay generic entry.
    - Barr agreed not to introduce generic Ovcon for five years in exchange for $20M.
  - FTC claimed that since Warner' s switch strategy could not be implemented in time, to delay generic entry it entered a horizontal agreement and paid Barr to stay out of the market.

Product Switching: Patent Settlements

- **FTC settled with Warner**
  - Abandoned portion of its agreement with Barr that prevented Barr from bringing a generic drug to market.
  - Prohibited from entering into any reverse settlement agreements for 10 years and would take affirmative steps to preserve the market for the first-generation form of its product.
    - No deletion of NDDF codes.
    - No destruction of/buy back of existing Ovcon.
  - Barr enjoined from entering any reverse settlements for 10 years.

Product Switching: Patent Settlements

- ***FTC v. Watson Pharm., Inc.*, 677 F.3d 1298 (11th Cir. 2012).**
  - Generic agreed not to enter market until 2015 and to abandon patent challenges in exchange for a share of Solvay's AndroGel (testosterone replacement) profits.
  - FTC alleged agreement is anticompetitive.
    - Solvay planned to introduce follow-on product before 2015 to switch market.
    - Follow-on product: Different dosage of AndroGel that would allow patients to use less gel and achieve the same therapeutic effects.

Product Switching: Patent Settlements

- **Held:**
  - Court affirmed dismissal of FTC's complaint.
  - Settlement lawful under the scope of the patent test. "[A]bsent sham litigation or fraud in obtaining the patent, a reverse payment settlement is immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent." *(Watson*, 677 F.3d at 1312).
- **FTC has Petitioned for certiorari.**
  - Question: "Whether reverse-payment agreements are *per se* lawful unless the underlying patent litigation was a sham or the patent was obtained by fraud (as the court below held), or instead are presumptively anticompetitive and unlawful (as the Third Circuit has held)?"

Product Switching: Patent Settlements

- ***FTC v. Cephalon Inc.***
  - FTC challenged patent settlement regarding generic entry of Cephalon's Provigil (promotes wakefulness).
  - Generic agreed not to enter market until 2012 in exchange for a share of Solvay's profits.
  - FTC alleged that the agreement was anticompetitive.
    - Cephalon planned to introduce follow-on product (Nuvigil) before 2012 to switch market.
    - Nuvigil is an isomer of Provigil.

Product Switching: Patent Settlements

- **Held:**
  - Cephalon's motion to dismiss denied.
  - "Scope of the patent" test.
    - Was patent procured by fraud?
    - Plaintiffs' theories alleged that the settlements granted rights beyond the scope of the patent:
      - Patent invalid, unenforceable and/or not infringed.
      - Prevented other generics from entering market.
      - Horizontal agreement not to compete.
      - Prevents entry of products not protected by patents.

Product Switching: Patent Settlements

- ***In re K-Dur Antitrust Litig.*, 686 F.3d 197 (3d Cir. 2012).**
  - Schering-Plough's sustained-release potassium chloride supplement used to treat side effects from blood pressure medication.
  - Agreement between Schering-Plough and generics to delay entry of generic product.
  - Plaintiffs (K-Dur wholesalers and retailers) asserted that they were forced to pay brand prices because generics kept off the market.
  - District Court: Presumed patent was valid, and only reverse payments that exceeded the scope of the patent or were made to settle objectively baseless suits would be subject to antitrust scrutiny.

Product Switching: Patent Settlements

- **3rd. Cir. Holding:**
  - Payment in exchange for delayed market entry in settlement of an ANDA suit is *prima facie* evidence of an unreasonable restraint of trade.
  - Scope of the patent test rejected.
  - "Quick look" rule of reason analysis adopted.
    - Patentee may rebut the presumption that such agreements are unreasonable restraints of trade:
      - Payment for a purpose other than delayed entry.
      - Payment offered some pro-competitive benefit.

Product Switching: Patent Settlements

- **Supreme Court petitions for cert:**
  - *In re K-Dur Antitrust Litig.* (3d Cir. 2012).
    - Whether the federal antitrust laws permit a brand name manufacturer that holds the patent for a drug to enter into a settlement of patent litigation with a prospective generic manufacturer, where the settlement includes a payment from the brand manufacturer to the generic manufacturer but does not exclude competition beyond the scope of the patent?
  - *FTC v. Watson* Pharm. (11th Cir. 2012).
    - FTC argued that it is a better vehicle for review, since *K-Dur was* a private cause of action while *Watson* "is brought by a federal agency charged by Congress with challenging unfair methods of competition."


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