HATCH WAXMAN-BUSINESS STRATEGIES

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PURPOSE OF THE ACT

- "To make available more low cost generic drugs by establishing a generic drug approval process for pioneer drugs first approved after 1962." H.R. Rep. No. 98-957, Pt. 1, at 14 (June 21, 1984).
- To strike "a balance between two potentially competing policy interests—inducing pioneering development of pharmaceutical formulations and methods and facilitating efficient transition to a market with low-cost, generic copies of those pioneering inventions at the close of a patent term." *Novo Nordisk A/S, et al. v. Caraco Pharmaceutical Laboratories, Ltd., et al.*, No. 2010- 1001 (Fed. Cir., April 14, 2010)

PRINCIPLE OF THE ACT

- Orange Book Listings of Patents covering the approved product by NDA Holder.
- Abbreviated New Drug Applications (ANDA)- Bioequivalence to NDA instead of extensive clinical testing.
- PIV certifications of ANDA holder with respect to orange book listed innovator’s patents alleging non-infringement/ invalidity/ unenforceability.
- Notice Letter to Patent Owner
- 45-Days for Patent Owner to Sue
- 30-Month Stay of FDA Approval of ANDA
- 180-Day Marketing Exclusivity for Successful First-Filer

Orange Book Patent Listing

- **Patents that can be listed**
  - Active ingredient (drug substance) and its crystal forms
  - Formulation or composition (drug product)
  - Method of approved use

- **Patents that may not be listed**
  - Processes
  - Packaging
  - Intermediates
  - Metabolites

HOW IS THE ACT BALANCED ?

Incentive for generic company- 180-day market exclusivity

- First applicant to submit a substantially complete ANDA (first-to-file)
- May be shared by multiple applicants
- Subject to forfeiture

Protection for NDA holder- 30-month stay of FDA approval

- If patent owner or NDA holder sues the ANDA applicant for patent infringement within 45 days of receiving notice of the Paragraph IV certification
- Runs from date of notification or expiration of NCE exclusivity
- May be lengthened or shortened by the court

A DELICATE BALANCE

Table 1

Hatch-Waxman: A Delicate Balance	
Encourage Competition	**Reward Technological Advance**
GENERIC MANUFACTURERS	**BRAND MANUFACTURERS**
• ANDA Process—only "bioequivalence" required • Allows Testing Before the Brand Patent Expires • Creates Incentive 180-Day Exclusivity—for first successful ANDA filer	• Defines the conditions for patent extensions -100% approval time + 50% testing time -up to max extension of 5 years -patent cannot be extended beyond 14 years • Non-Patent Exclusivity -NDA data kept as proprietary by FDA -5 years' data exclusivity for New Chemical Entity -excluding salts or esters -3 years' data exclusivity for improvements to approved brand products via clinical trials (eg, new uses, dosage form, dosage regimens) • Sets forth a process for patent challenges

HOW DO GENERICS POSITION THEMSELVES?

- **TARGET PRODUCT**
  - For some the target could be everything
  - For some generics it could be only products which are fetching above 100 Million USD per annum
  - For some only those products which have a a very high barrier to entry and cannot be made by all generic companies

- **Market Position**
  - Most generics eye the first to file position
  - Some are just follow on- blindly follow or piggy back on the strategy of first filer

SOME OF THE "ACTUAL" GENERIC STRATEGIES

- We plan to continue to expand our Global Division through targeted ANDAs and a first-to-file and first-to-market strategy. Our products and product candidates are generally difficult to formulate and manufacture, providing certain barriers to entry for potential competitors. **(Impax Laboratories, Form 10-K)**

- The "Niche Generics" program is targeted on developing those generic drug products that are: Difficult to develop for technical reasons, especially injectable and ophthalmic dosage forms. No or very limited API source **(InnoPharma, Company Website)**

- We believe that we can maximize the profitability of our generic product opportunities by continuing our proven track record of bringing to market high quality products that are difficult to formulate or manufacture, or for which the API is difficult to obtain. **(Mylan, Form 10-K)**

- The strategy in the Rx Pharmaceuticals segment is to be the first to market with those new products that are exposed to less competition because they have more difficult to develop formulations and cost much more to complete. **(Perrigo, Form 10-K)**

- We constantly seek to expand our range of generic products, with an emphasis on high-value products, including those with high barriers to entry. **(Teva, Form 20-F)**

- Our strategy in the U.S. is to develop generic pharmaceuticals that are difficult to formulate or manufacture or will complement or broaden our existing product lines. **(Watson, Form 10-K)**

- Differentiation is one of the rudiments that success thrives on and the company strategically selects difficult to develop, high technology products and niche markets to get ANDA approvals.**(Wockhardt, Annual Report 2011)**

Source : Thomson Reuters and Financial Express

AGGRESSIVE STRATEGIES ADOPTED BY GENERICS AND INNOVATORS

- Generics- At-risk generic launches (before the completion of trial based on a success at preliminary injunction)
- Generics- Agreement with innovator for delaying launch and hence parking exclusivity and preventing other generics from marketing
- Innovator- Authorized generic deals for eroding the market of generics.
- Innovator- Misuse of orange book by listing irrelevant patents like indications not directly approved for the drug
- Innovator- Pay for delay settlement agreements with generics
- Innovator- Filing citizens petitions to freeze generic approval

CASE LAW- EXAMPLE 1

- **2004**- Teva and Sun (first filers) had challenged the Protonix patent's validity in seeking U.S. Food and Drug Administration approval for a generic version. Wyeth and patent holder Altana Pharma—now part of Nycomed—had filed a patent-infringement lawsuit that year.
- **2007**- New Jersey district court denied Altana's motion for a preliminary injunction. The lower court found that the patentee had failed to prove two critical prerequisites of equitable preliminary relief: (1) a likelihood of success on the merits and (2) irreparable harm. Generics " launched at risk" immediately after that.
- Sales of branded Protonix plunged 80% to $395 million for 2008
- **2010**- A jury in federal court in New Jersey upheld the patent's validity and found Teva's / Sun's product in infringement. The decision was upheld in FC.
- **2013**- Innovator obtained damages for at risk launch from both companies. Teva will pay Pfizer and Takeda $1.6 billion and Sun will pay $550 million. Teva will pay $800 million in 2013 and the remaining $800 million by October 2014; Sun's entire payment will be made in 2013. As part of the settlement, both Teva and Sun have admitted that their sales of generic pantoprazole infringed the patent that was held valid by the court

CASE LAW – EXAMPLE 2

- Andrx is first to file a Paragraph IV ANDA for a generic bioequivalent to Hoechst's popular drug Cardizem
- Hoechst sues alleging infringement and the suit is settled as follows
- The Settlement
  - Andrx agrees not to market its generic for at least 18 months *after* the 30 month stay expires
  - Andrx is paid $40 million/year to stay off in the event it loses the suit and $60 million/year if it wins
  - Andrx agreed to retain the 180 day exclusivity

CASE LAW- EXAMPLE 3

- The Federal Circuit ruled, in *Novo Nordisk A/S, et al. v. Caraco Pharmaceutical Laboratories, Ltd., et al.*, No. 2010- 1001 (Fed. Cir., April 14, 2010), that "the Hatch-Waxman Act authorizes a counterclaim only if the listed patent does not claim *any* approved methods of using the listed drug."
- *Novo Nordisk* involved a change by the NDA Holder in the "use code narrative" that expanded the use description for the product, Prandin®, a change that caused the FDA to deny Caraco's "carve out," based upon the original "use code."
- Caraco, the generic manufacturer, counterclaimed under MMA provisions, to challenge the change in "use code."
- The Federal Circuit reversed the trial court's grant of summary judgment on this "de-listing" issue, and its grant of an injunction requiring Novo Nordisk to reinstate the prior "use code."

InterParte Review in HW Litigation

- The 2011 Leahy–Smith America Invents Act ("AIA") has provided an expedited *Inter Partes* Review ("IPR") process to challenge issued patents before the U.S. Patent and Trademark Office ("USPTO").
- IPR is an adjudicative proceeding before the Patent Trial and Appeal Board ("PTAB") rather than a traditional patent examination. It permits anyone other than the patent owner to challenge a patent's validity for alleged obviousness or lack of novelty based on patents or printed publications**.**
- Like *inter partes* reexamination, the IPR petitioner is foreclosed from raising, in court, invalidity challenges that were raised or could have been raised in its IPR which may discourage use of the procedure by some generic manufacturers. Unlike *inter partes* reexamination, which generally took several years to reach appeal at the USPTO making that procedure unattractive to generic companies, IPR is a relatively fast proceeding, concluding in 12–18 months.
- If the petitioner or real party in interest files an invalidity challenge in district court on or after the date on which the petitioner files a petition for IPR, the district court case is automatically stayed. Otherwise, the decision on whether or not to stay court proceedings is left to the court's discretion.

Biosimilars-HW

- This combination is still evolving- Watch out this space for more on this topic- Thank you !!

Thank you !

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