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New Strategies Arising from the Hatch-Waxman Amendments
#4888

New Strategies Arising From the Hatch-Waxman Amendments

Practicing Law Institute Telephone Briefing

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I. INTRODUCTION AND BACKGROUND PADDEN

- History of Hatch-Waxman Act
- Background of Amendments
- Key Changes and Topics of Presentation
  - 30 Month Stay
  - Declaratory Judgments
  - Wrongful Listing of Patents
  - 180 Day Exclusivity
  - Settlement Agreements

II. 30 Month Stay (Myers)

A. Only one 30-month stay per ANDA

Applicants certify only to patents listed in the Orange Book at time ANDA filed. § 1101(a)(2)(A)(ii)(I), creating new 21 U.S.C. § 355(j)(5)(B)(iii).

Subsequently listed patents cannot require new certification and new 30-month stay.

B. Applicant cannot effectively shorten 30-month stay by amending a previously filed ANDA to include a different drug. Applicant is prohibited from amending or supplementing its application to seek approval for a listed drug different from the listed drug in its original application.

C. Amendments to an ANDA for different strengths of the listed drug are allowed. *See* §1101(a)(1)(B) creating new 21 U.S.C. §355(j)(2)(D)(i) & (ii).

D. An ANDA will be approved before the expiration of the 30-month stay upon a judgment by the District Court that the patent is invalid or not infringed.

III. Declaratory Judgments (Padden)

The Act now explicitly authorizes ANDA applicants to bring actions for declaratory judgment in certain circumstances. *See* §1101(a)(2)(C) creating new 21 U.S.C. §355(j)(5)(C)(i).

A. What are the requirements?

1. Patent owner and NDA holder must fail to sue within 45 days of Paragraph IV notification

2. If the Paragraph IV notification claims non-infringement ANDA applicant must offer confidential access to application; if Paragraph IV certification is based solely on invalidity of the patent, confidential access not required

B. What is the right?

". . . the courts of the United States shall, to the extent consistent with the constitution, have subject matter jurisdiction in any action brought by [the ANDA applicant] under section 2201 of title 28 for a declaratory judgment that such patent is invalid or not infringed." 35 U.S.C. § 271(c)(5)

C. Pre-Amendment Declaratory Judgment Analysis

?? *Dr. Reddy's Laboratories, Ltd v. Pfizer Inc.*, 2003 WL 21638254 (D. N. J.)

?? *Teva Pharmaceuticals USA, Inc. v. Pfizer Inc.*, 69 U.S.P.Q. 2d 1791, (D. Mass 2003)

1. Present Activity That Could Infringe

- established by ANDA

2. Reasonable Apprehension of Suit

(a) listing patent in Orange Book

(b) refusal to grant covenant not to sue

(c) assertion of patents against others

(d) desire of patentee to preserve exclusivity of co-opted first filer

3. Discretion

D. Does this amendment expand right to Declaratory Judgment in Hatch-Waxman litigation?

No - jurisdiction can only extend to limits of constitution and 28 U.S.C. 2201 already provides for remedy

Yes - shows legislative policy in favor of resolving patent issues before commercialization

- pro DJ policy of amendments should affect exercise of discretion

E. Potential New Strategies

1. Disclosure of ANDA product

- required by amendments

- not enough for DJ jurisdiction in Teva v. Pfizer

- amendment may give greater weight to this factor

2. Estoppel argument if brand name fails to sue

(a) conduct that misleads defendant to infer that patentee does not intend to enforce patent

(b) reliance on misleading conduct

(c) prejudice

3. Strategies upon late listing of patents

(a) Infringement Suit by NDA holder.

?? ANDA applicants are not <u>required</u> to notify NDA holders of additional paragraph IV certifications for late listed patents, but ANDA applicants will likely <u>want</u> to do so in order to precipitate litigation of the new patent

?? NDA holders will not get additional stay but will still usually want to sue for injunction barring the generic entry.

(b) DJ action by ANDA applicant

?? Fact of suit/judicial economy

?? Estoppel argument if NDA holder fails to sue without good reason

4. Strategies upon filing of second ANDA

(a) NDA holders – still have incentive to sue because they still get 30 month stay, unless they have a settlement with the first applicant that effectively excludes other generics for longer than the 30 month stay

(b) ANDA applicants – if NDA holder does not sue, second applicant has more incentive to seek DJ because district court decision of invalidity or non-infringement in the first action no longer triggers exclusivity period

- Second applicant's likely argument (see FTC argument in Teva v. Pfizer.):
    - constitutional injury requirements satisfied because patent holder delayed entry of second applicant by settling with first applicant and then not suing second; the only way for second applicant to advance the date of its market entry is by a favorable court decision in DJ action.

IV. Wrongful Listing (Myers)

A. Prior to amendments, courts held that there was no private right of action.

B. ANDA applicant may seek order requiring that patent be removed from Orange Book listing on grounds that patent does not claim the approved drug or an approved method of using the drug

B. A wrongful Orange Book listing can be challenged only as a counterclaim. Challenger still does not have an independent basis for action. §1101(a)(2)(C) creating new 21 U.S.C. §355(j)(5)(C)(ii.

C. No money damages may be awarded to challenger, only delisting. §1102(a)(1).

V. 180 Day Exclusivity (Myers/Padden)

See §1102(a)(1) and (2) creating new 21 U.S.C. §355(j)(5)(B)(iv) and (D).

A. Who is entitled to 180 day exclusivity?

?? All first applicants, i.e., all applicants who submit substantially complete ANDAs with paragraph IV certifications on the same day will enjoy shared exclusivity.

B. What is the 180-day exclusivity period?

?? Starts when the first applicant first markets the ANDA product or the NDA product

?? Only one 180-day exclusivity period, regardless of shared exclusivity or subsequent patent listings.

C. Events of Forfeiture

1. Failure to Timely Market

Generic must market its drug within 75 days after the later of:

(a) the first applicant's approval becomes effective (up to a maximum of 30-month after filing ANDA) and

(b) a final favorable decision for any applicant with respect to the patents to which the first applicant certified, either by settlement, appellate court decision or withdrawal of the patent from the Orange Book.

Effects: – A second applicant can still precipitate the running of the exclusivity period, but now an appellate court decision is necessary to force the issue.

?? Generics have time to ramp up after decision

2. Failure to Effectively Pursue Approval at FDA

Exclusivity is forfeited upon:

(a) Failure to obtain tentative FDA approval within 30 months of filing ANDA

(b) Withdrawal of ANDA by applicant or decision by FDA to deem the application withdrawn for substantive reasons

(c) Withdrawal or amendment of Paragraph IV certification

Effects:

?? No more file first and figure out paragraph IV certification later

?? Pressure for FDA approval in 30-months

Related Provisions:

?? Notice of Paragraph IV certification must be given within 20 days of filing

?? If Paragraph IV certification is included in subsequent amendment or supplement, notice of certification must be provided when the supplement or amendment is submitted.

3. Expiration of Listed Patent

4. Agreement in Violation of Antitrust Laws

?? Must be final decision of FTC or Court of Appeals

?? Does not prohibit all agreements to delay entry

?? What about delayed entry settlement blessed by FTC?

VI. Settlement Agreements (Padden)

A. What Agreements Must Be Filed with Federal Antitrust Authorities?

?? Agreements (and related documents) among ANDA applicants making paragraph IV certifications and brand name drug companies or other generics making paragraph IV certifications on the same drug re:

(a) 180 day exclusivity or

(b) Manufacturing, marketing or sale of the ANDA drug or the brand name drug

See §1111-1113.

B. What Agreements Need Not Be Notified To Antitrust Authorities?

?? Under §1112(c)(1) Agreements need not be notified if they solely concern:

?? Purchase orders for raw material supplies

?? Equipment and facility contracts

?? Employment or consulting contracts

?? Packaging and labeling contracts

?? Money only settlements

?? Walk away settlements

C. Can ANDA litigation be settled with an agreement that the generic drug will not be marketed in exchange for a payment from the NDA holder?

YES - *In re Tamoxifen Citrate Antitrust Litigation*, 277 F.Supp.2d 121 (5-15-03) (settlement not made in bad faith and no antitrust injury)

NO - *In re: Cardizem Antitrust Litigation*, 332 F.3d 986 (6th Cir. 2003) (6-13-03) (per se unlawful)

MAYBE - *Valley Drug Co. v. Geneva Pharmaceuticals*, 344 F.3d 1294 (11th Cir. 2003) (9-15-03) (rule of reason)

YES - *Asahi Glass Co. Ltd v. Pentech Pharmaceuticals, Inc.*, 289 F.Supp.2d 986 (N.D.Ill.2003) (Posner, J.) (10-29-03)

NO - *In re Schering-Plough Corp.*, F.T.C. No. 9297 (12-18-03) (illegal under modified rule of reason)

1. In re Tamoxifen Citrate Antitrust Litigation

Key Facts/Findings:

?? Settled on appeal after District Court held that patent was invalid and unenforceable.

?? Brand paid generic $21M and licensed generic to sell in U.S.

?? Settlement required that District Court vacate its opinion of invalidity and unenforceability.

?? Other generics subsequently challenged patent and the courts found the patent valid and enforceable.

Key Legal Principle/Findings:

?? Allegations of bad faith settlement for anticompetitive purposes can state a claim for violation of the Sherman Act, but the allegations here did not suffice.

?? The claimed antitrust injury resulted from the patent, not the settlement. The other generics were excluded by reason of the patent, not the settlement.

2. In re Cardizem Antitrust Litigation

Key Facts/Findings:

?? ANDA drug was outside of the claimed range of the patent.

- ?? Generic agreed not to market generic product until final favorable decision in patent action.

- ?? Generic agreed not to give up its 180-day exclusivity.

- ?? Brand agreed to pay $10M per quarter.

Key Legal Principle/Findings:

- ?? Delay of first generic also delayed others.

- ?? Not merely an attempt to enforce patent rights (Agreement extended to generic drugs not at issue in litigation).

- ?? Settlement was horizontal agreement to eliminate competition and therefore *per se* unlawful.

3. Valley Drug Co. v. Geneva Pharmaceuticals

Geneva Agreement:

- ?? Geneva agreed not to sell any form of terazonsin (even approved capsule form) until (a) patent expired (b) another generic entered, or (c) final judgment is entered finding non-infringement and invalidity

- ?? Geneva agreed not to transfer rights to exclusivity and to oppose other ANDA's

- ?? Abbott agreed to various payments during pendency of litigation and upon final decision

Zenith Agreement:

- ?? Zenith's delisting claim and Abbott's infringement claim dismissal

- ?? Zenith acknowledged validity of patents and coverage of products by patents

- ?? Zenith agrees not to sell any form of terazonsin until (a) patent expires, or (b) another generic enters

- ?? Zenith agrees not to aid entry by other generics

- ?? Abbott agrees to quarterly payments and to not claim infringement if Zenith markets after other generic enters

Key Legal Principles/Findings:

- ?? Payment from patentee to alleged infringer should not be automatically condemned under antitrust laws.

- ?? Agreements not illegal per se where ANDA products infringed brand's patent.

- ?? Court must consider the exclusionary power of the patent before condemning agreements as unlawful under the antitrust laws.

- ?? Reasonableness of agreements must be judged at time of execution; subsequent finding of invalidity does not render agreements improper (unless patent procured by fraud or known to be invalid).

- ?? Provisions of the Agreements found to have exclusionary effects beyond that of the patent will be subject to traditional antitrust analysis to assess competitive effect and possible § 1 violation.

4. Asahi Glass Co. Ltd. v. Pentech Pharmaceuticals, Inc.

Key Facts/Findings:

- ?? Asahi was supplier of active ingredient in ANDA product for Pentech; Asahi did not market competing drug.

- ?? Patent found valid but not infringed by subsequent generic product; decision appealed.

- ?? Glaxo and Pentech settled ANDA litigation with agreement that:

  a. Pentech was licensed to sell drug in Puerto Rico immediately and in U.S. upon entry by others.

  b. Glaxo provided drug free of charge and received a royalty.

- ?? Second Applicant (Apotex) obtained judgment that patent was valid but not infringed and entered market

- ?? Pentech started marketing in U.S., but sourced drug from Glaxo

Key Legal Decisions:

- ?? Asahi has no standing because it is not in the market that was allegedly divided, the market for the sale of the pharmaceutical drug.

- Antitrust claim must be dismissed because settlement cannot be attacked as an antitrust violation unless it is "almost certain" that the patent would be found invalid and not infringed by generic product.

- Posner found patent valid in other litigation and there was no suggestion that infringement claim was frivolous.

- Settlement lead to increased competition because generic was able to enter earlier than otherwise.

- Questions criticism of "reverse payment" settlements but notes that pioneer did not pay generic to stay out of the market here.

5. In re Shering Plough

Settlement: Generic (Upsher) agreed to delay entry for a period of years and licensed certain products to brand name manufacturer (Schering) in exchange for payment by Schering.

Key Findings/Holding:

- Reverse payments "raise a red flag" but are not illegal per se or inherently suspect.

- "If there has been a payment from the patent holder to the generic challenger, there must have been some offsetting consideration. Absent proof of other offsetting consideration, it is logical to conclude that the quid pro quo for the payment was an agreement by the generic to defer entry beyond the date that represents an otherwise reasonable litigation compromise."

- Parties could not show that consideration was for lawful purpose, (e.g. "cash starved" generic; litigation costs; real value from licenses).

- " Under the standard we adopt here, if the parties simply compromise on the entry date, standing alone, they need not worry about a later antitrust attack."

- No need to address merits of patent dispute.

    - Must examine settlement with uncertainties at time of settlement.

    - After the fact examination not reliable because parties change tune.

    - After the fact analysis of patent dispute would reduce certainty.

D. What conclusions can be drawn from these decisions?

1. Courts will consider whether the settlement goes beyond enforcement of the patent.

2. Settlements will be evaluated on the basis of the knowledge at the time of settlement.

3. Settlements that merely delay entry by the generic, without any payment by the pioneer in excess of the generic's litigation costs, will likely be approved by the FTC.