

The Generic Industry's Role and Co-existence with the Patented Pharmaceutical Industry :: A Discussion on U.S. Policy and Legislation

International Intellectual Property Institute

Intellectual Property and the Economics of
International Public Health

October 7, 2003

Raymond A. Kurz

Hogan & Hartson LLP

555 Thirteenth Street, NW

Washington, D.C. 20004

(202) 637-5600

∴ Purpose of the Hatch-Waxman Act:

n The Hatch-Waxman Act was among the first legislative attempts to balance innovation, competition and prescription drug affordability.

n **Innovation**: The Hatch-Waxman Act seeks to encourage innovation by restoring some of the patent term lost during the drug development and approval process, and by providing procedures to resolve patent disputes in a timely manner.

n **Affordability**: The Hatch-Waxman Act contains various provisions to foster the generic drug industry, such as an abbreviated FDA application process (ANDA) and the ability to use patented technology in seeking FDA approval.

❖ Key Provisions of the Hatch-Waxman Act

The Paragraph IV Certification

- n NDA Holder Lists Pertinent Patents in the Orange Book.
- n Generic Must Show Bioequivalence and Must Certify to Patents Listed in Orange Book.
- n Four Certification Options:
 - (I) no patent information on the drug product that is the subject of the ANDA has been submitted to the FDA;
 - (II) there was a patent which has expired;
 - (III) such patent will expire on a particular date; or
 - (IV) such patent is invalid or will not be infringed by the manufacture, use or sale of the drug product for which the ANDA is submitted.

:: Consequence of a Paragraph IV Certification

:: The 30-Month Automatic Stay

n ANDA filers certifying under Paragraph IV must provide notice to patent owners and NDA holder.

n Innovator drug company has 45 days to initiate a patent suit.

n If a patent infringement suit is filed within 45 days, FDA approval of the ANDA is automatically stayed until the earliest of:

(I) the date the patents expire,

(II) the date a final determination of non-infringement is entered in the patent infringement litigation, or

(III) the expiration of 30-months from the patentee's receipt of notice of the Paragraph IV certification.

Non-Concurrent 30-Month Stays: Incentive to Innovate or “Evergreening”?

Arguments For Non-Concurrent 30-Month Stays:

Non-concurrent 30-month stays arose when a brand-name company listed an additional patent in the Orange Book after the generic applicant filed its ANDA. The generic must recertify to this later-listed patent. If the brand-name company filed another infringement suit within 45-days, an additional 30-month stay was triggered.

- n Foster continued innovation.
- n It is the 180-day period of exclusivity that promotes early ANDA filings, increasing the likelihood of multiple patents/litigations.

Non-Concurrent 30-Month Stays: Incentive to Innovate or “Evergreening”?

Arguments Against Non-Concurrent 30-Month Stays:

- n Promotes “Evergreening.”
- n Innovator companies may extend their market exclusivity.
- n Improper Orange Book listings.

⚡ Legislation and Rulemaking Address the 30-Month Automatic Stay.

PROVISION	CURRENT LAW	H.R. 1 and S.1	FDA Regulation 21 C.F.R. § 314
The 30-Month Stay	Once the patent owner brings an infringement suit, a 30-month stay is triggered.	Permits only one 30-month stay and only for those patents listed in the Orange Book at the time of the filing of a Paragraph IV ANDA.	Permits only one 30-month stay by providing that each ANDA applicant need only provide one notice per ANDA.
Orange Book Listings	No provisions: No FDA review and no private right of action to challenge Orange Book listings.	If patent owner does not sue within 45 days of Paragraph IV certification, ANDA applicant may request declaratory judgment. If patent owner does sue, generic may file a counter claim to challenge Orange Book listing.	Requires NDA applicants to list patents claiming the active ingredient as well as formulation and method of use patents. Prohibits NDA holders from submitting patents claiming packaging, metabolites or intermediates, process patents and unapproved uses.

:: Another Consequence of a Paragraph IV Certification

:: The 180-Day Exclusivity Period

n The first applicant submitting an ANDA which contains a Paragraph IV certification is granted market exclusivity for a period of 180 days from the earlier of:

- (I) the date of a court decision holding the patent invalid or not infringed; or
- (II) the date the generic manufacturer begins marketing the drug.

Failure to Trigger the 180-Day Exclusivity Period: Circumstances Currently Generating Controversy.

1. Settlement Agreements Whereby the Generic Agrees not to Enter the Market :

- n By not entering the market, the generic does not begin commercial marketing and therefore does not trigger the 180-day period.
- n This, in turn, precludes FDA from approving any eligible subsequent generic applicants.

2. Marketing the Brand-Name Product as Generic, Rather than Under the ANDA:

- n The brand-name company supplies the generic with the brand-name drug product, so that the generic applicant could market it as a generic version.
- n It is not clear whether this activity constitutes “commercial marketing” sufficient to trigger the 180-day exclusivity.

❑ Two Bills Pending in Congress Contain Provisions to Amend the Hatch-Waxman Act.

PROVISION	CURRENT LAW	H.R. 1 and S.1
Triggering the 180-Day Exclusivity Period	Triggered by earliest of (1) day the drug is first commercially marketed; or (2) the day a court decision holds that the patent is invalid or not infringed.	Requires first ANDA applicant to forfeit 180-day exclusivity under certain circumstances including failure to market within a specified time frame.
Agreements Between Branded and Generic	No provisions	Agreements regarding sale or manufacture of generic drug equivalent to patented drug must be submitted to FTC and Assistant Attorney General within 10 days of completion.