

# Generic Drug Entry Prior to Patent Expiration: *An FTC Study (July 2002)*

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# Overview

- Hatch-Waxman established a regulatory framework that sought to balance incentives for continued innovation by brand-name companies and opportunities for market entry by generic drugs.
  - Generic drugs now comprise more than 47% of prescriptions filled – up from 19% in 1984.
- In spite of this record of success, the Study found that 2 provisions governing generic drug approval prior to patent expiration (the 30-month stay and the 180-day marketing exclusivity) are susceptible to strategies that, in some cases, may have prevented the availability of more generic drug products.
- These provisions continue to have the potential for abuse.

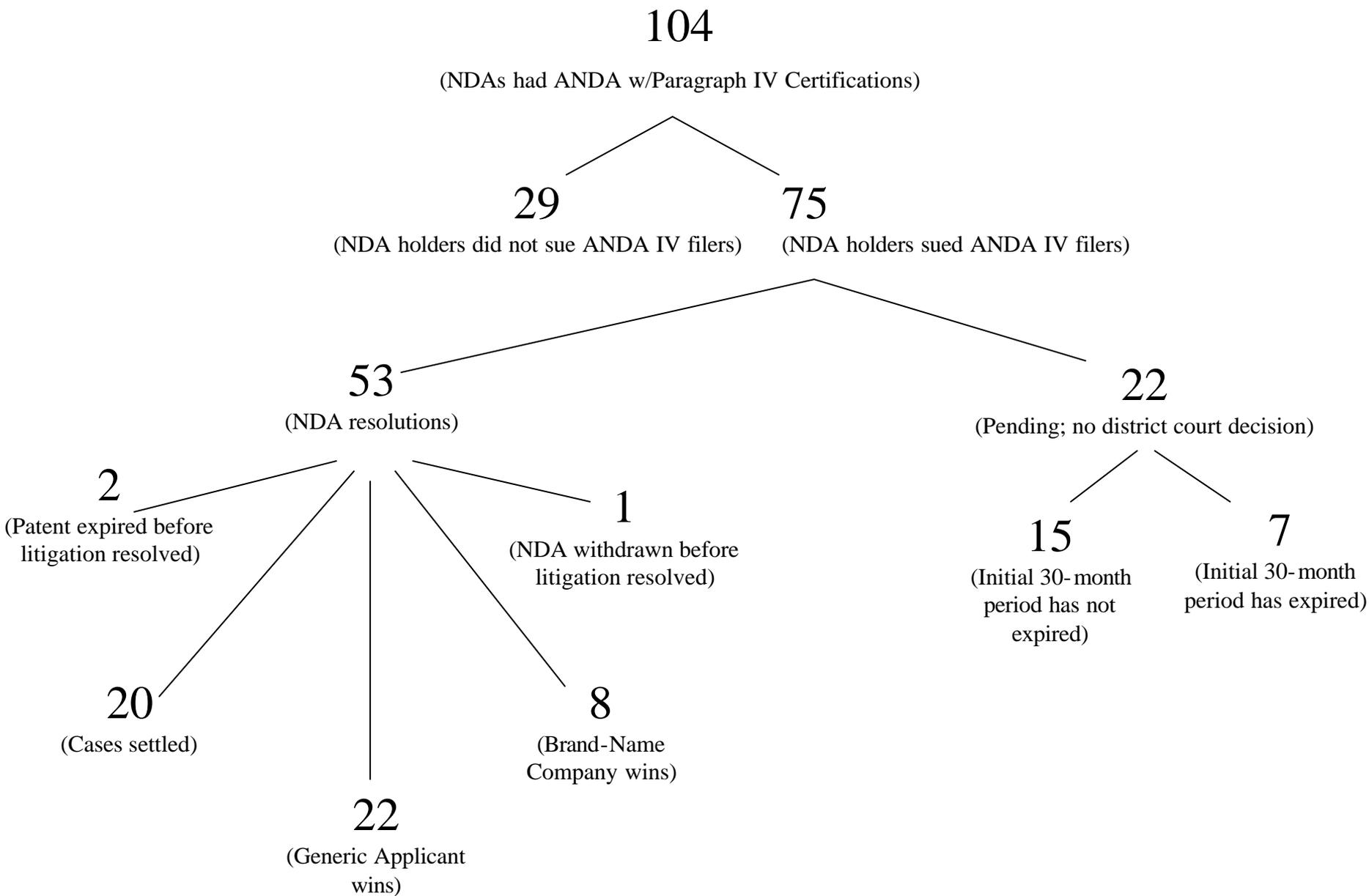
# Key Terms of the Hatch-Waxman Amendments

- ANDA
  - An abbreviated new drug application used to seek approval of a generic drug product.
- Paragraph IV Certification
  - The brand-name company's patents are invalid or not infringed by the ANDA.
- Orange Book
  - The FDA's listing of patents that claim brand-name drug products.
- 30-Month Stay
  - A 30-month stay of FDA approval of an ANDA is invoked if a brand-name company receives notice of the generic applicant's ANDA that contains a paragraph IV certification and files suit for patent infringement within 45-days of that notice.
- 180-Day Marketing Exclusivity
  - The first generic applicant to file an ANDA containing a paragraph IV certification is awarded 180-days of marketing exclusivity, upon its commercial marketing or a court decision, during which the FDA may not approve a subsequent generic applicant's ANDA for the same drug product.

# Scope of the FTC Study

- In October 2000, the FTC announced its intent to undertake a study of how generic drug competition has developed under Hatch-Waxman.
- April 2001, FTC received clearance from OMB to conduct the study.
- The FTC issued nearly 80 special orders pursuant to Section 6(b) of the FTC Act to brand-name and generic companies.
  - The special orders were focused on brand-name drug products that were the subject of Paragraph IV certifications filed by generic applicants.
  - Only NDAs in which a generic applicant notified a brand-name company with an ANDA containing a Paragraph IV certification after 1/1/92 and prior to 1/1/01 were included in the study.
  - The selection criteria resulted in 104 drug products, as counted by unique NDAs filed with the FDA.
  - These 104 drug products included “blockbuster” drugs such as Capoten, Cardizem CD, Cipro, Claritin, Paxil, Pepcid, Pravachol, Prilosec, Prozac, Xanax, Zantac, Zocor, and Zolofl.
- Responses to the special orders were generally completed by the end of December 2001.

Figure 2-1 Summary of Brand Company and 1<sup>st</sup> ANDA IV Filer Activity



# Patent Listing Practices

- Two new phenomena appear to be emerging in relation to patent listing practices that affect patent litigation
  1. An increase in the number of patents listed in the Orange Book for “blockbuster” drug products.
  2. The listing of patents after an ANDA has been filed for a particular drug product.

# Increase in the Number of Patents in the Orange Book

- For drug products with substantial annual net sales, brand-name companies are suing generic applicants over more patents.
  - Since 1998, for 5 of the 8 “blockbuster” drug products, the brand-name company alleged infringement of 3 or more patents.
  - This compares to 1 of 9 “blockbuster” drug products as to which the brand-name company filed suit against the first generic applicant prior to 1998 for 3 or more patents.
- In the future, patent infringement litigation may take longer to resolve than the historical average of 25 months and 13 days from complaint filing date to district court decision.

# Listing Patents in the Orange Book After an ANDA Has been Filed

- In 8 instances, brand-name companies have listed later-issued patents in the Orange Book after an ANDA has been filed. Most of these have occurred since 1998.
- By listing patents in the Orange Book after an ANDA has been filed, brand-name companies can obtain additional 30-month stays of FDA approval.
- For the 8 drug products, the additional delay of FDA approval (beyond the first 30 months) has ranged from 4 to 40 months. In all 4 cases so far with a court decision, the patent has been found either invalid or not infringed by the ANDA.

# Listing Practices

- Most of the later-issued patents (in the 8 cases) raise questions about whether the FDA's patent listing requirements have been met.
- The Study describes 3 categories of patents that raise significant listability questions.
  - Patents that may not be considered to claim the drug formulation or method of use approved for the NDA by the FDA;
  - Product-by-process patents that claim a drug product produced by a specified process; and
  - Patents that constitute double-patenting because they claim subject matter that is obvious in view of the claims of another patent invented by the same person.
- Recent court decisions have held that Hatch-Waxman does not provide generic applicants a basis on which to challenge the listing of any of these patents.

# Recommendation: 30-Month Stay Provision

- Permit only one automatic 30-month stay per drug product per ANDA to resolve infringement disputes over patents listed in the Orange Book prior to the filing date of the ANDA.
- This should eliminate most of the potential for improper Orange Book listings to generate unwarranted 30-month stays.
- Also, clarify when brand-name companies can sue generic applicants for patent infringement by overruling *Allergan, Inc. v. Alcon Labs, Inc.*

# Additional Concerns about Patent Listings

- The FDA currently does not review the propriety of patents listed in the Orange Book, and courts have ruled that applicants do not have a private right of action to challenge a listing.
- The lack of such a mechanism may have real world consequences in that the Commission is aware of a least a few instances in which a 30-month stay was generated solely by a patent that raised legitimate listing questions. At a minimum, it appears useful for the FDA to clarify its listing regulations.
- Another remedy that may warrant consideration would be to permit a generic applicant to raise listability issues as a counterclaim in patent infringement litigation already in progress.

# 180-Day Marketing Exclusivity

- Prior to 1992, the FDA granted 180-day exclusivity to 3 generic applicants.
- Between 1993 and 1997, the FDA did not grant 180-day exclusivity to any applicants.
- Since 1998, the FDA has granted 180-day exclusivity to the first generic applicant for 31 drug products.

# Triggers of the 180-Day Marketing Exclusivity

- For 19 of the 31 drug products, “commercial marketing” triggered the 180-day exclusivity. For the other 12 drug products, a “court decision” triggered the 180-day exclusivity.
- In most instances, generic applicants have waited to enter the market until at least a district court has held the patent covering the brand-name drug product was invalid or not infringed by the ANDA.

# Patent Settlements and the 180-Day Marketing Exclusivity

- The data showed that there were 20 final settlements between the brand-name company and the first generic applicant.
- 3 Types of Final Patent Settlements
  1. 9 involved brand payments to the generic applicant
  2. 7 licensed patents to the generic applicant
  3. 2 allowed the generic applicant to market the brand-name drug product prior to patent expiration.
- 14 of these agreements had the potential to park the 180-day exclusivity for some period of time.

# Recommendation: 180-Day Exclusivity

- To mitigate the possibility of abuse of the 180-day exclusivity provision, the Study recommends that Congress enact the Drug Competition Act, S. 754 as introduced by Senator Leahy, to require brand-name companies and generic applicants to provide copies of certain agreements to the FTC.

# 3 Minor Recommendations – Based on Conduct Observed

1. Clarify that “commercial marketing” includes the first generic applicant’s marketing of the brand-name drug product.
2. Codify that the decision of any court on the same patent being litigated by the first generic applicant constitutes a “court decision” sufficient to trigger the 180-day exclusivity.
3. Clarify that a court decision dismissing a declaratory judgment action for lack of subject matter jurisdiction constitutes a “court decision” sufficient to trigger the 180-day exclusivity.

# Conclusions

- Hatch-Waxman Amendments have been successful in encouraging generic entry.
- The 30-month stay and the 180-day marketing exclusivity provisions should be amended to ensure that the provisions are not gamed to delay or deter generic entry.