The Generics Pathway in the USA: the American experience, a model for the world?

Prof. Frederick M Abbott
Foro Latinoamericano
ALIFAR-ANAFAM
Mexico City
May 15, 2012

The USA market is unique

- High-priced, high-volume originator patented drug sales
- Low-priced, high-volume generic drug sales
- Few direct price controls, but significant government involvement – federal and state - in drug procurement
- Private sector distribution of drugs controlled by a small number of companies

General observations

- USA generics pathway fiercely competitive on price
- Key profit potential represented by 180-day market exclusivity based on Paragraph IV certification
  - Patent challenge buyouts remain controversial
- On the whole, the generics pathway in the USA works reasonably well
  - introduces low-price generics into the market shortly following patent expiration or successful challenge to patent validity
- *Is the USA a model for other countries?*

Patent and market exclusivity basics

- Patents 20-years from filing date, plus up to 5-year extension for new chemical/molecular entities
- Very wide range of patentable subject matter
  - Multiple new uses, modes of delivery, dosages, patient populations
- Patents and uses listed in Food and Drug Administration (FDA) "Orange Book" – including after initial approval
- 5-year market exclusivity following first approval of new drug (with additional 3-year exclusivity based on new clinical investigation, 6-month for pediatric formulations)

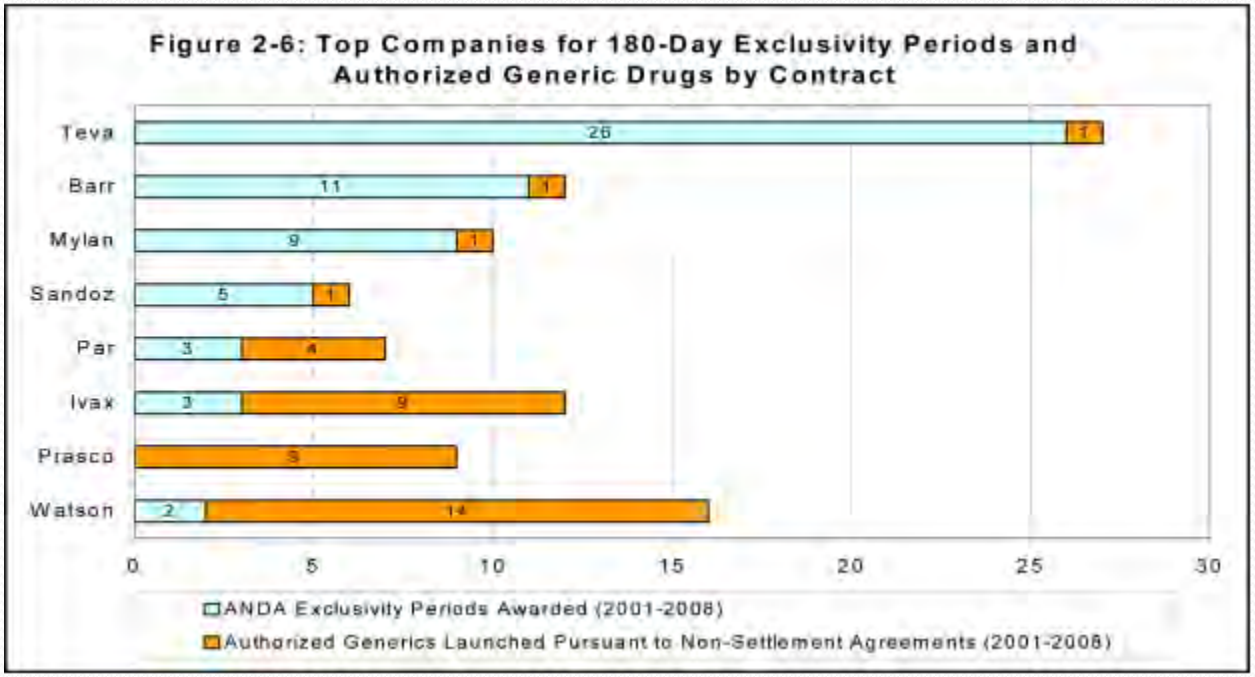
Generics pathway

- Abbreviated new drug application (ANDA) requires a showing of bioequivalence, and manufacturing data
- May request authorization upon patent expiration, or indication of no patent coverage (or patent expired)
- Paragraph IV certification acknowledges potential blocking patent, but asserts invalidity or non-infringement
- Patent owner files infringement action, staying FDA approval for 30 months (or court decision)

180-day exclusivity

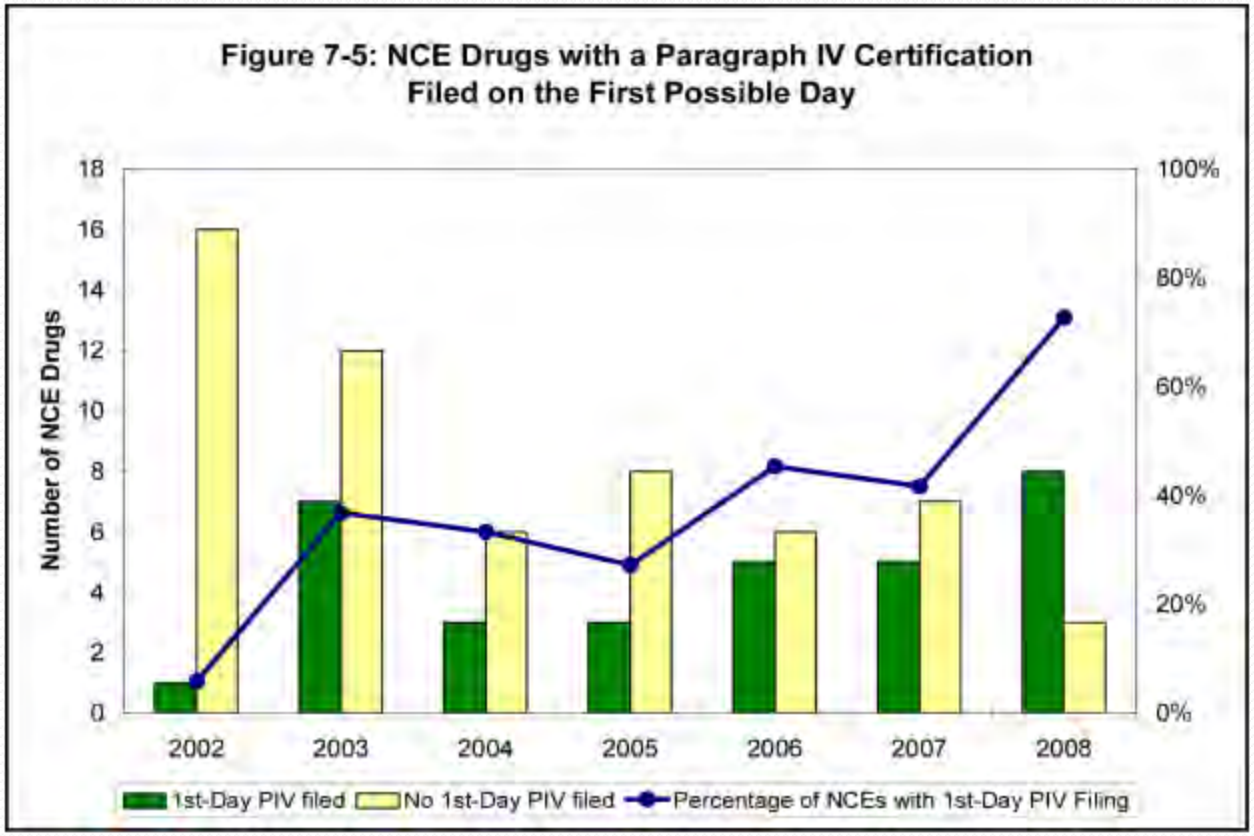
- First Paragraph IV certifier may earn 180-day market exclusivity for generic upon FDA approval to enter market
- Marketing exclusivity may now be shared among all "first day" filers
  - First day may be determined for NCEs as one year prior to expiration of 5-year market exclusivity
- 2011 FTC Study indicates that "shared exclusivity" has not deterred Paragraph IV certifiers

Top Paragraph IV certifiers



Source: US Federal Trade Commission, Authorized Generic Drugs: Short-Term Effects and Long-Term Impact, Aug. 2011

Trends in first day filings



Source: US Federal Trade Commission, Authorized Generic Drugs: Short-Term Effects and Long-Term Impact, Aug. 2011

Complexity based on “uses”

- ANDA filers may only seek approval for “approved uses”
- Originator volumes often attributable to (lawful) physician prescriptions for unapproved uses
- Originators seek to block FDA approvals based on patents not covering ANDA applied-for uses
- Originators argue that generic producers intend to sell for unapproved uses (just as the originators!)
- Courts have largely sided with generic applicants

Settlements – “pay for delay”

- Patent holders typically seek to settle Paragraph IV certification actions by offering variety of incentives
  - Distribution license for covered product
  - Licensing of other technologies
  - Cash payments
- Federal Trade Commission considers inconsistent with purpose of Hatch-Waxman Act, and violation of antitrust (competition) laws
- Federal courts have not endorsed FTC approach
  - Allows settlements within scope of patent holder rights

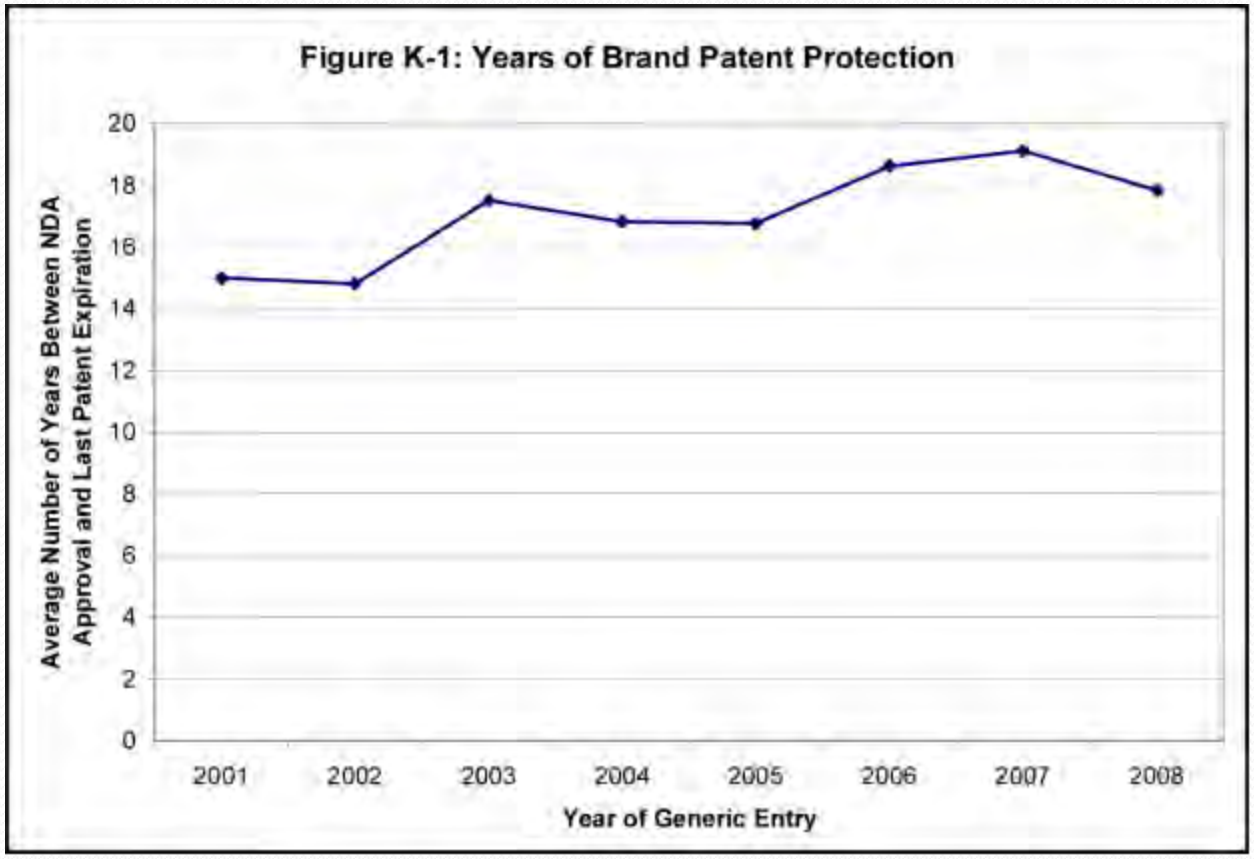
Authorized generics

- Patent holders may introduce “unbranded” generic during 180-day market exclusivity period to maintain share of sales
- Theoretically reduces incentive for Paragraph IV certification by generic applicants
- 2011 FTC Study finds that generic applicants are not deterred from filing, but concludes that risk remains from incentive for settlements

Key characteristics of US pathway

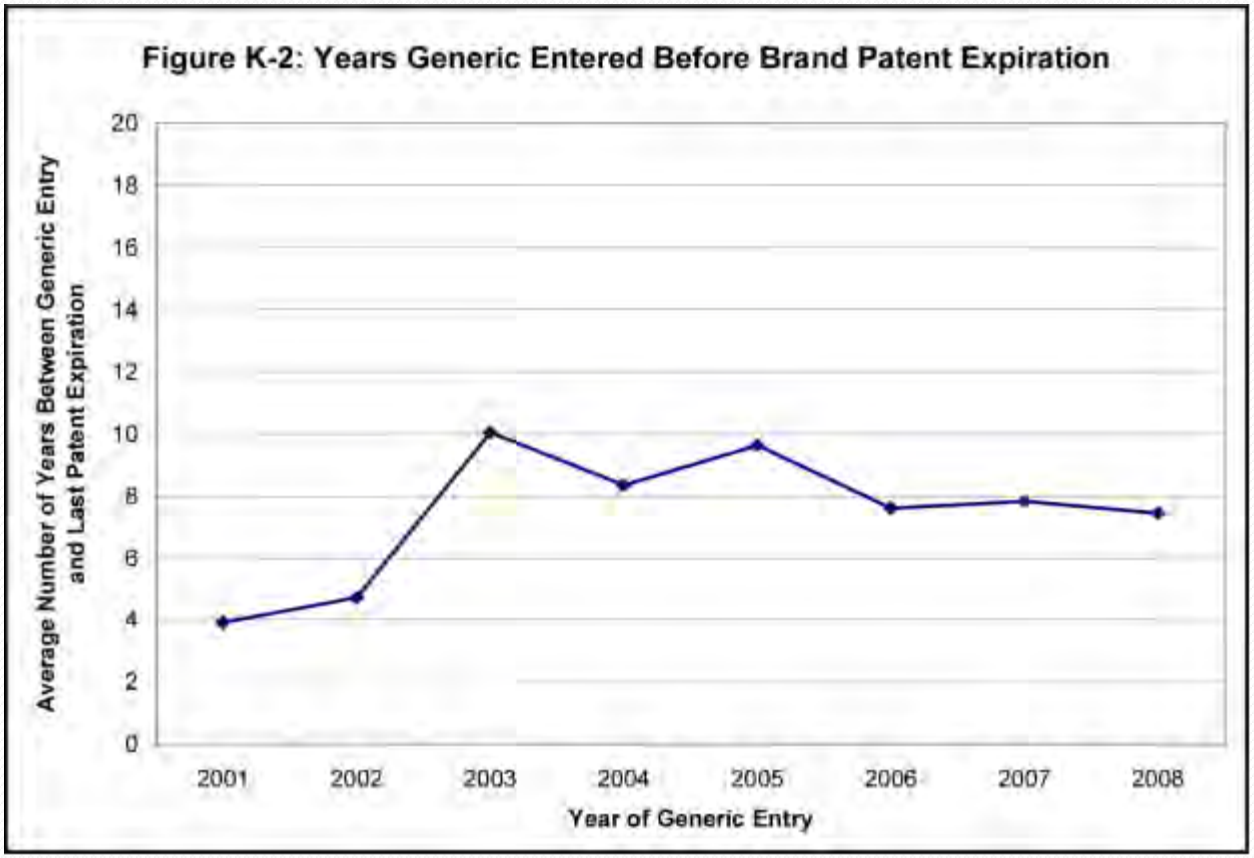
- Significant financial incentive to pursue Paragraph IV certification
  - Costs of patent litigation in the millions of US dollars
- Well-developed government institutions overseeing originator-generic competition
  - FTC, Department of Justice, States Attorney Generals
  - Also, active consumer groups
- Competent independent judiciary with developed jurisprudence
- Pharmaceutical benefit providers increasingly sensitive to price

Initial period of Brand Patent Protection



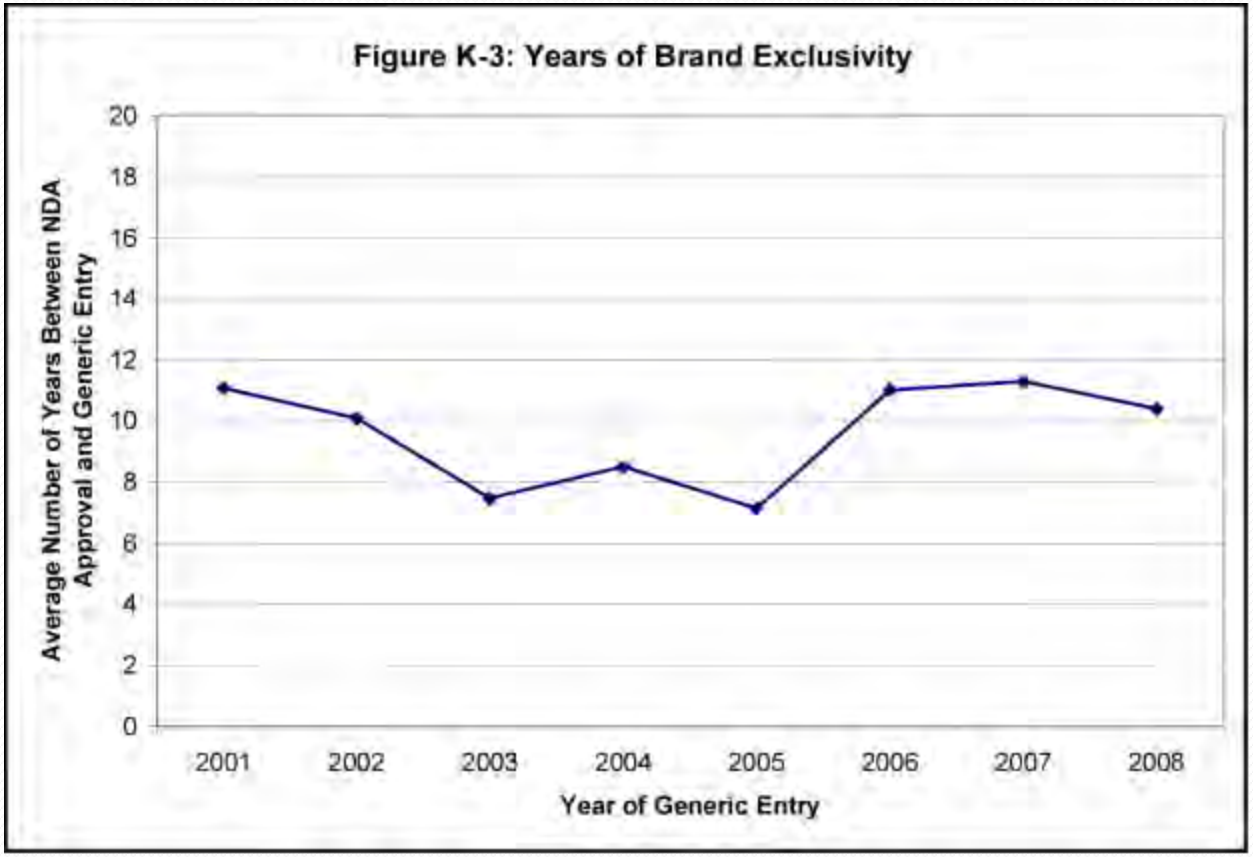
Source: US Federal Trade Commission, Authorized Generic Drugs: Short-Term Effects and Long-Term Impact, Aug. 2011, at K-1

Generic Entry before Patent Expiration



Source: US Federal Trade Commission, Authorized Generic Drugs: Short-Term Effects and Long-Term Impact, Aug. 2011, at K-2

Actual years of Brand Exclusivity



Source: US Federal Trade Commission, Authorized Generic Drugs: Short-Term Effects and Long-Term Impact, Aug. 2011, at K-3

A model for the world?

- US FTA program moves partner countries toward USA patent and Hatch-Waxman pathway model
  - Texts are not uniform
  - Patent scope extended to new uses and methods of use
  - Generally require 5-year minimum market exclusivity (including based on data submitted in another Party); with additional 3-year period for new clinical investigation
  - Linkage between marketing approval and patents; revised Colombia, Panama and Peru texts more specifically incorporate Hatch-Waxman analogs

Trans-Pacific Partnership

- Goes further on patents to eliminate possibility for India Patent Act Section 3(d)

Article 8.1 (Patents) "… the Parties confirm that: patents shall be available for any new forms, uses, or methods of using a known product; and a new form, use, or method of using a known product may satisfy the criteria for patentability, even if such invention does not result in the enhancement of the known efficacy of that product." (USTR Proposal of Feb. 10, 2011)

- Essentially mirrors USA market exclusivity periods

TPP Linkage

- Linkage between patents and marketing approval very similar to Hatch-Waxman
  - Patent holders receive notice and opportunity to block
  - Automatic stay of approval
  - Successful generic challenger should receive reward
    - Includes footnote to cover multiple same day challengers
  - Benefits of market exclusivity provisions may depend on timely request for approval
    - USTR asserts benefit to country of application by accelerating entry of new drug products

Impact on non-USA markets?

- Potential for increased patenting based on broader subject matter scope may extend period of higher prices
- Potential for delays to generic entry based on potential lengthening of market exclusivity
- Generic producers outside USA required to independently seek invalidation or determination of noninfringement of local patents
  - Rule of “independence” from Paris Convention
- Few generic companies positioned to spend millions for entry to markets less lucrative than USA

Positive impact on R&D

- Thesis of USTR is that allowing USA-based originators to return higher revenues leads to their increased investments in R&D, which results in introduction of new and better medicines in all markets
- Probably some validity to this point: even discounting for wasteful practices and inefficiencies, some percentage of revenues goes into new drug R&D
- Most R&D conducted in the USA with support of advanced infrastructure
- No secret that from standpoint of USTR, TPP is a "mercantile" project intended to improve USA exports and balance of payments

A modest proposal to reduce impact of TPP-type obligations

- Rule of independence of patents generally provides that invalidity and non-infringement determinations in one country do not have effect in other countries
- TPP and other FTAs introduce extraterritorial effect of marketing approval as basis for exclusivity
- TPP and FTAs could provide that determinations of patent invalidity (or non-infringement) in originator country result in *de facto* invalidity (or non-infringement) in other partner countries
  - Would minimize need for generic producers in partner countries to replicate expensive litigation
  - Do not extend to patent granting

Overall assessment

- Hatch-Waxman type generic pathway works reasonably well in the USA
- For most other countries, particularly developing countries, reduced market size and gaps in comparable institutional capacity suggest that introduction of comparable pathway will favor multinational originators
- Countries can invest in institutional capacity, and work to facilitate patent challenges, but it is difficult to match capacity of multibillion-dollar originator legal teams