

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

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The United States experience is unique in terms of the pricing and availability of medicines. On one side, originator patented medicines are sold in volumes and at prices exceeding those for the rest of the world -- it is the most highly valued market for the originator companies.¹ On the other side, prices for generic medicines are likely the lowest among OECD countries,² and perhaps for almost all countries. US consumers use large quantities of generic medicines.

There are characteristics of the USA pharmaceuticals market that warn against oversimplification. The government is a large-scale purchaser and insurance provider for drugs. Private distribution of drugs in the United States is under the control of a relative handful of large-scale distribution companies that use their distribution networks and purchasing power to bargain for low prices from manufacturers, and typically prefer to purchase across a range of products. It is not a market that is easy to enter profitably.

The regulatory environment is complex and strict, and companies face a continuing threat of tort-based liability lawsuits from end-users.

The generics pathway is fiercely competitive. Only at the early stages of patent expiration may generics companies enjoy a relatively high profit margin. The "gold cup" of the generics manufacturer is the 180 day market exclusivity period that may be earned through a paragraph IV certification challenge under the Hatch-Waxman Act. Today, the typical generics company pursuing a paragraph IV challenge is likely to be tempted by a lucrative settlement offer. As a result of a Court of Appeals for the Federal Circuit statutory interpretation, the-180 day market exclusivity period may now be shared among several generics producers.

There are serious issues confronting the USA in terms of its approach to providing access to healthcare broadly, and medicines specifically. There are issue areas surrounding the Hatch-Waxman Act, including refinement of the analysis by which courts weigh the anticompetitive impact of "reverse payment" settlement agreements,³ and continued "gaming" of the system by the originators. But, on the whole,

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¹ *The Global Use of Medicines: Outlook Through 2015*, Report by the IMS Institute for Healthcare Informatics, e.g., slides 3-5, May 2011.

² U.S. Department of Commerce, International Trade Administration, *Pharmaceutical Price Controls in OECD Countries, Implications for U.S. Consumers, Pricing, Research and Development, and Innovation*, Wash., DC, December 2004, at 21-24 (hereinafter "DOC Pricing and R&D").

³ In June 2013 the US Supreme Court decided that buyout settlements of generic producer patent challenges by patent owners are subject to "rule of reason" assessment under the antitrust laws. *Federal Trade Commission (FTC) v. Actavis*, U.S. Sup. Ct., 526 U. S. 756 (2013).

the generics pathway in the USA produces a reasonably good result in terms of getting generic drugs onto the market in a reasonable period of time. I will suggest, however, that the elements necessary to make this system work in the USA are not present in most other countries, and that the temptation to transpose the USA system to other countries should be approached with caution.

1. Some patent and market exclusivity basics for the USA

The generics pathway in the USA is the counter-balance to the system for the patenting of medicines. In the USA, the patent term is generally 20 years from the filing date of the application, but for medicines an extension for up to five years may be secured based on the length of the regulatory approval process. The five-year period is calculated by taking one-half the duration of clinical testing under an investigational new drug application (INDA), plus the time following submission of the New Drug Application (NDA). One may assume that with minor variation, the NCE/NME drug product enjoys a patent term of 25 years from the filing of the application. But, an extension can only be granted with respect to the first commercial marketing of a drug, not for variations of the "same" drug.⁴

Many of the complications along the generic pathway are introduced by the possibility to obtain patents for things other than a new chemical entity or new molecular entity. The US PTO will grant patents for minor variations in molecular structure, for new uses of known compounds (such as for second, third, etc. medical indications), for new methods of delivery (including differences in dosages), for new target populations (for example, by age group), and for other variations.

When a new drug application (NDA) is submitted to the US Food and Drug Administration, the applicant provides information concerning the patents relevant to that drug. Those patents are listed in the so-called Orange Book. The NDA applicant, after the grant of marketing approval, may update Orange Book listings, including adding patents for new uses, etc., that may have been secured subsequent to the initial request for approval, and must provide information concerning approved uses under specific patents.⁵ The FDA does not screen or evaluate substance of these Orange Book submissions.

In the United States, the period of marketing exclusivity following approval of a new chemical entity-based drug is relatively brief, five years. The architects of the Hatch-Waxman Act deliberately kept the exclusivity term short, and assumed that it would not typically outlast the term of a patent covering the same drug. There are possibilities for additional 3-year market exclusivity terms based on new clinical investigations, and 6-month extensions for pediatric formulations.

Marketing exclusivity in respect to new biologics drugs approved by the FDA under legislation adopted in 2009 extends for 12 years,⁶ and the FDA continues to refine its rules for approval of biosimilar products. The decision by Congress to authorize 12 years of marketing exclusivity for biologics was (and

⁴ 35 USC §156; US PTO Manual of Patent Examining Procedures, §1.720.

⁵ See *Caraco Pharmaceutical Laboratories v. Novo Nordisk*, US Sup. Ct., 132 S.Ct. 1670 (2012).

⁶ Biologics Price Competition and Innovation Act of 2009, Pub. L. No. 111-148, §§ 7001-7003, 124 Stat. 804 (2010) [hereinafter BPCI] (Title VII, Subtitle A of PPACA).

remains) controversial, and the United States has proposed to incorporate this standard in the Trans Pacific Partnership (TPP) agreement under negotiation.

2. The ANDA process

The originator company first seeking approval from the FDA for a new drug, or subsequently seeking approval for a new indication, must submit detailed information concerning the conduct of clinical trials and results, and information concerning the manufacturing process for the drug.⁷ This is all part of the new drug application or NDA process. The generic applicant submits an abbreviated new drug application, or ANDA, which requires the applicant to demonstrate that its chemical compound is bio-equivalent to the originator compound, along with information concerning manufacturing.⁸ The ANDA applicant is not required to submit data concerning clinical trials. It is permitted to rely upon the approval secured by the originator-holder of the commercial marketing approval.

The generic producer may submit an ANDA requesting that marketing approval be effective upon the expiration of the applicable patents of the originator. It may submit an ANDA indicating that there is no relevant patent (or that any patents have expired). Or, it may indicate that there is a patent that covers the drug or applicable use, but that the patent is invalid, or that the applicant will not infringe any relevant patent. The last route is referred to as a paragraph IV certification deriving from the relevant statutory citation.⁹ The originator holder of the patent identified in a paragraph IV certification may (and usually does) respond by initiating a patent infringement lawsuit against the ANDA applicant in federal court. This results in an automatic 30-month stay of the requested FDA approval for the generic, which time may be shorter based on a decision of the federal court.

In order to encourage challenges to originator patents, the Hatch-Waxman Act provides that the first challenger under paragraph IV is entitled to a 180-day period of market exclusivity following approval of the ANDA. As one might imagine, being the only generic supplier during a six-month period would be an extremely valuable prize for a generic producer. But, nothing is so simple.

The FDA initially interpreted the Hatch-Waxman Act to provide that the 180-day marketing exclusivity period would be awarded to the first successful generic challenger of a patent under paragraph IV. However, this interpretation was rejected by the Court of Appeals for the Federal Circuit, which said that the language referred to the first party to submit a paragraph IV certification to the FDA. Initially, the FDA was then prepared to award the 180-day market exclusivity period to the first generic company that submitted an ANDA with a paragraph IV certification (and whose ANDA application was approved). The consequence was a chaotic race to file the first application, the formation of a tent city in the parking lot of the FDA for weeks prior to the first available date for filing an ANDA, and violence or threat of

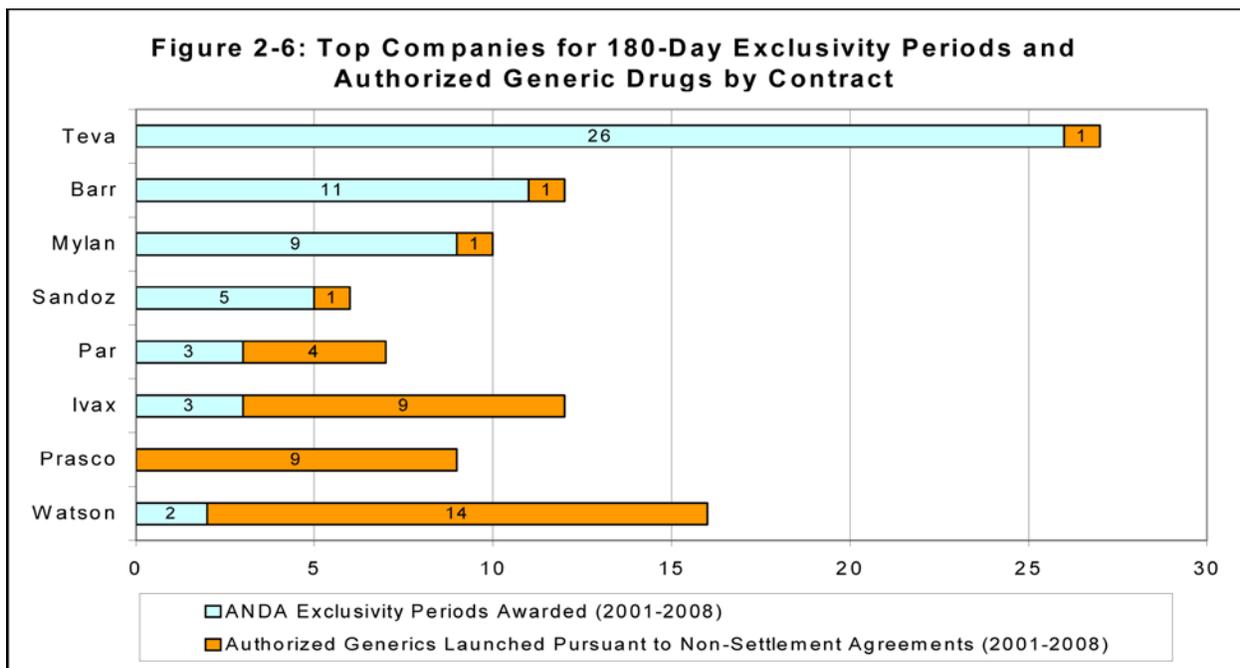
⁷ US Food and Drug Administration, New Drug Applications (NDA), <<http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/NewDrugApplicationNDA/default.htm>>.

⁸ US Food and Drug Administration, *Generic Drugs: Information for Industry* <<http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/ucm142112.htm>>.

⁹ 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

violence among those sent to file the application.¹⁰ The FDA feared for the safety of its personnel. This led to a change in the rule such that any application received on the same "first day" would be eligible for the 180-day marketing exclusivity. The exclusivity might now be shared.

The FDA has suggested that the possibility for a complete overlap of shared exclusivity is limited since ANDA applicants are not likely to receive marketing approval at the same time, and that in any case this provides an incentive to complete the application and approval process. It has from time to time hinted at the consideration of a new rule, but so far without taking action. Data compiled by the US Federal Trade Commission suggests that the foreseeability of shared exclusivity has not significantly deterred generics companies from filing paragraph IV certification challenges.¹¹

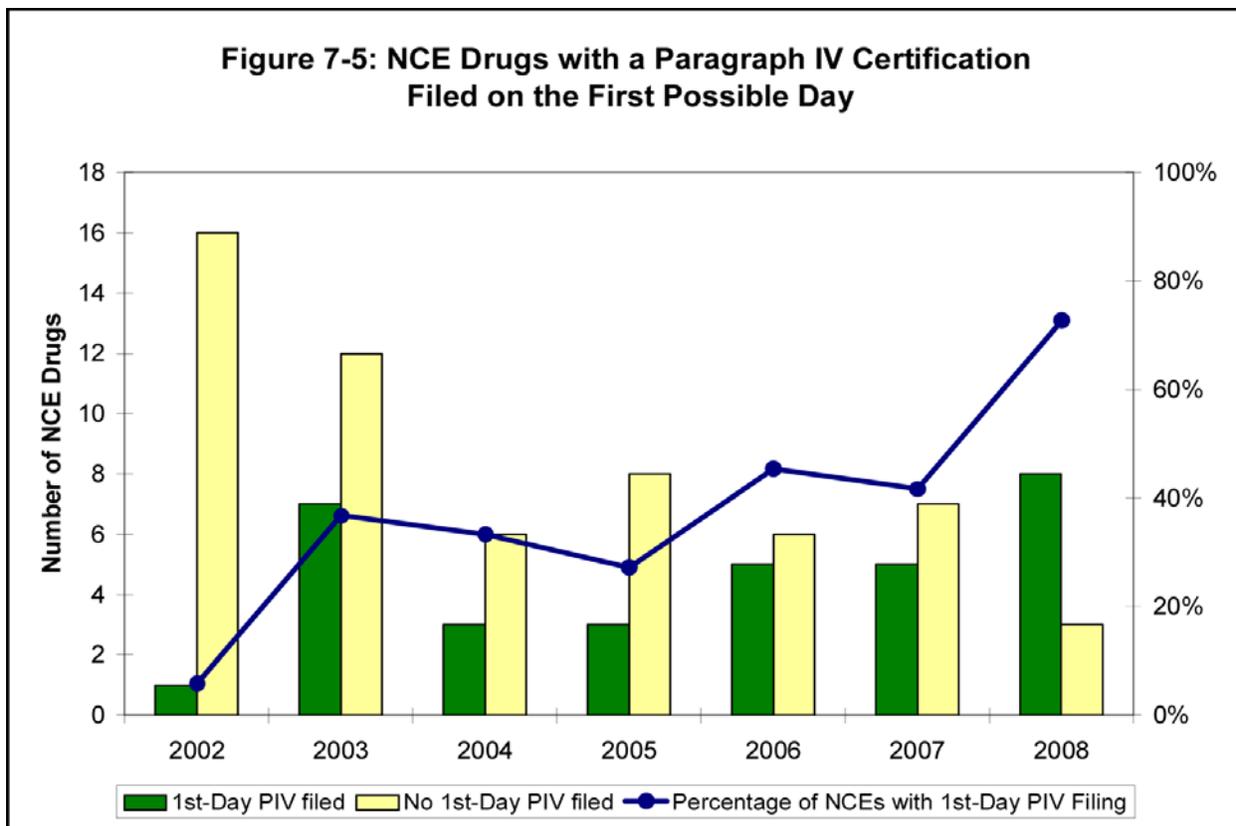


Source: US Federal Trade Commission, *Authorized Generic Drugs: Short-Term Effects and Long-Term Impact*, Aug. 2011, at 25.

In a substantial number of cases, it is possible for potential ANDA applicants to determine what is the "first day" for submitting an application, which is one year prior to the expiration of the five-year market exclusivity period for the originator product. The products eligible for market exclusivity are limited to the first recipient of commercial approval for a new entity, and a limited number of other products for which additional clinical research has been conducted, so that shared exclusivity will be relevant only in some cases.

¹⁰ See US FDA (CDER) Guidance for Industry 180-Day Exclusivity When Multiple ANDAs Are Submitted on the Same Day, July 2003, and; US Federal Trade Commission, *Authorized Generic Drugs: Short-Term Effects and Long-Term Impact*, Aug. 2011, at 134 (hereinafter "FTC Authorized Generics").

¹¹ FTC Authorized Generics, at 133-137.



Source: US Federal Trade Commission, *Authorized Generic Drugs: Short-Term Effects and Long-Term Impact*, Aug. 2011, at 135.

Much of the complexity of the Hatch-Waxman system arises from the fact that the FDA approves drugs for specific uses. A compound is directed to the treatment of a disease, or a number of diseases or conditions. These are the "approved uses". Physicians may prescribe the same compound to treat conditions that are not included among the approved ones for the drug on the theory that this is an exercise in medical professional discretion. But, the originator companies (and generic companies) are not permitted to market their drugs for "unapproved uses".¹² As the courts have acknowledged, the highest volume of sales for some drugs are for unapproved uses.

An ANDA applicant may not ordinarily seek approval for marketing for an unapproved use. But, ANDA applicants may file paragraph IV certifications with respect to approved uses where the originator believes that the generic company is intending to market for unapproved uses. Or, generic ANDA applicants may seek to market for uses as to which patents have expired, but for which the originators

¹² See, e.g., Peter Loftus and Brent Kendall, *Abbott to Pay \$1.6 Billion*, Wall St. J., May 7, 2012 (updated)"Abbott Laboratories agreed to pay \$1.6 billion and to plead guilty to a criminal misdemeanor violation of a federal drug law following allegations that the company improperly promoted antiseizure drug Depakote for unauthorized uses".

continue to hold use patents that have not expired. Again, the originators may believe that ANDA applicants are intending to market for uses that are covered by approved use patents.

This is, of course, an interesting problem. One can readily argue that the US PTO should not be granting a proliferation of patents for the same product, and that generic producers are justified in gaming the system to circumvent those patents, allowing doctors to determine the conditions for which drugs are prescribed. The originators conversely argue that their incentives to seek approval for new uses are diminished if the generic producers can readily cross over into the new territory.

3. Paragraph IV settlements, reverse payments, etc.

In recent years, the biggest threat to the successful operation of the Hatch-Waxman paragraph IV mechanism has been the use of patent settlements by originator and generic companies. The originator companies have a major financial incentive to prevent the early marketing of generic versions of their products. Rather than risk invalidation (or a determination of non-infringement) of their patents, they prefer to pay paragraph IV ANDA certifiers to settle their patent infringement claims. These settlements may involve offering distribution licenses for the products covered by the patent or other products, licensing of technologies, and/or direct cash payments. If the originator can settle with each of the companies that is potentially entitled to a 180 day market exclusivity period, it will have eliminated most of the incentive for generic companies to pursue patent invalidity (or non-infringement) litigation which is quite expensive.

The US Federal Trade Commission has been extremely unhappy about the use of patent litigation settlements to prevent the early entry of generics. In 2013 the U.S. Supreme Court acted largely in favor of the FTC to resolve a split among federal circuit courts that had been somewhat unreceptive to the FTC's position, holding that so-called "reverse payment" settlements were *not* immunized from antitrust scrutiny even if they were within the legitimate zone of patent protection.¹³ Instead, the Supreme Court held that patent law and antitrust law function side-by-side with different policy objectives, and that large unexplained payments from patent owners to generic challengers are suspect under the antitrust laws. The Court said:

"An unexplained large reverse payment itself would normally suggest that the patentee has serious doubts about the patent's survival. And that fact, in turn, suggests that the payment's objective is to maintain supracompetitive prices to be shared among the patentee and the challenger rather than face what might have been a competitive market—the very anti-competitive consequence that underlies the claim of antitrust unlawfulness."¹⁴

The Court noted that both the patent owner and the generic challenger may benefit from a reverse payment settlement—the patent owner maintaining its monopoly (and pricing power) and the generic producer receiving valuable consideration (i.e. a share of those monopoly profits)—but that consumers

¹³ *Federal Trade Commission (FTC) v. Actavis*, U.S. Sup. Ct., 526 U. S. 756 (2013).

¹⁴ *Id.*, at [].

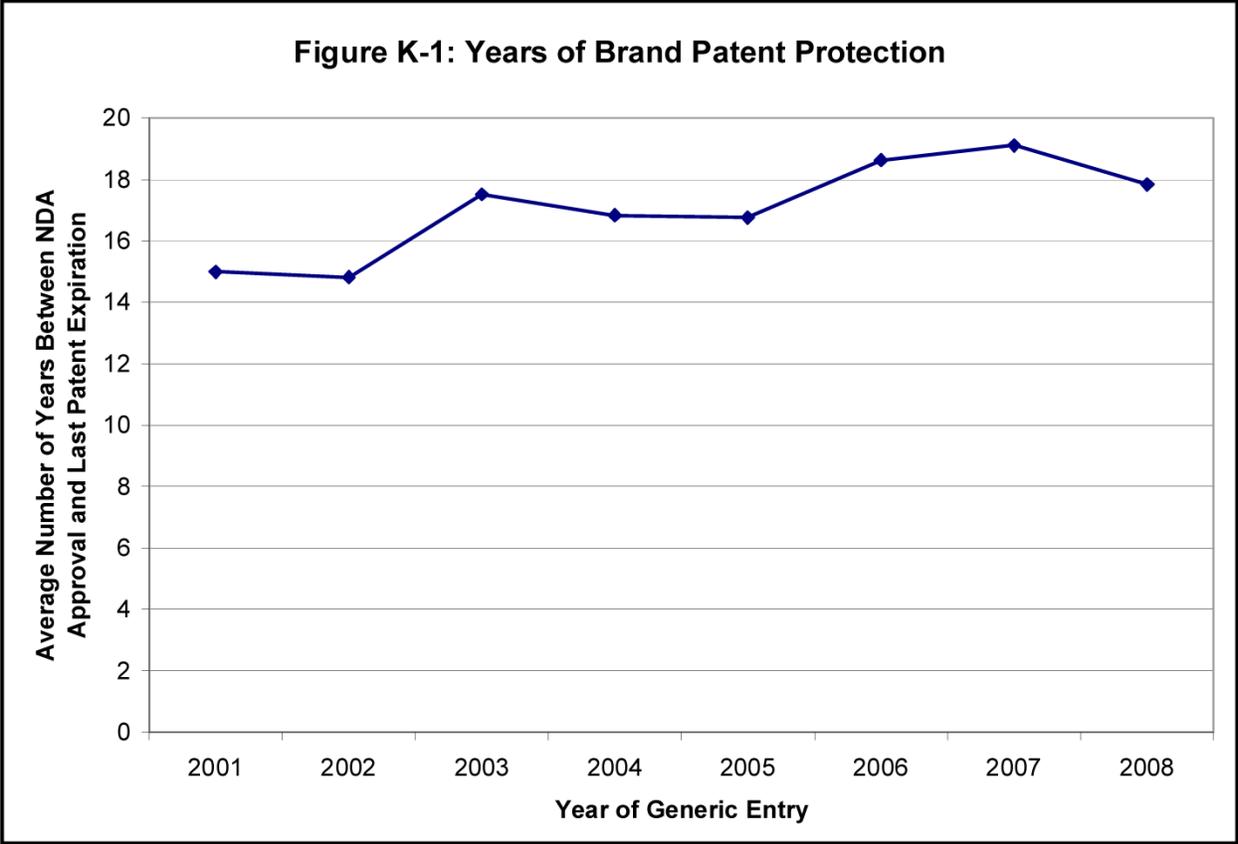
lose because of the delay in initiation of generic competition. The Supreme Court's decision re-invigorated the FTC's challenge to reverse payment settlements, but questions remain to be resolved regarding the standards by which courts assess whether there is a large unexplained payment from patent owner to generic challenger.¹⁵ Another complication with the Hatch-Waxman Act system involves the practice of originator companies to introduce "authorized generics" during the 180-day market exclusivity period (if and when it is earned by a generic producer or producers). Rather than ceding the generics market to third companies, the originator introduces a generic version of its product, going into competition with the holder of the 180-day exclusivity. While the US FTC has been critical of this practice on the theory that it may undermine the incentives for third-party generic producers to challenge patents, a recent FTC study concluded that, on one hand, potential competition from the originator did not appear to inhibit generic patent challenges (though it did reduce the profitability of the 180 day marketing exclusivity period). On the other hand, the FTC expressed considerable concern that originators were using their potential to introduce authorized generics as a way to induce generic challengers to patent settlements.¹⁶

4. Assessment of the US system

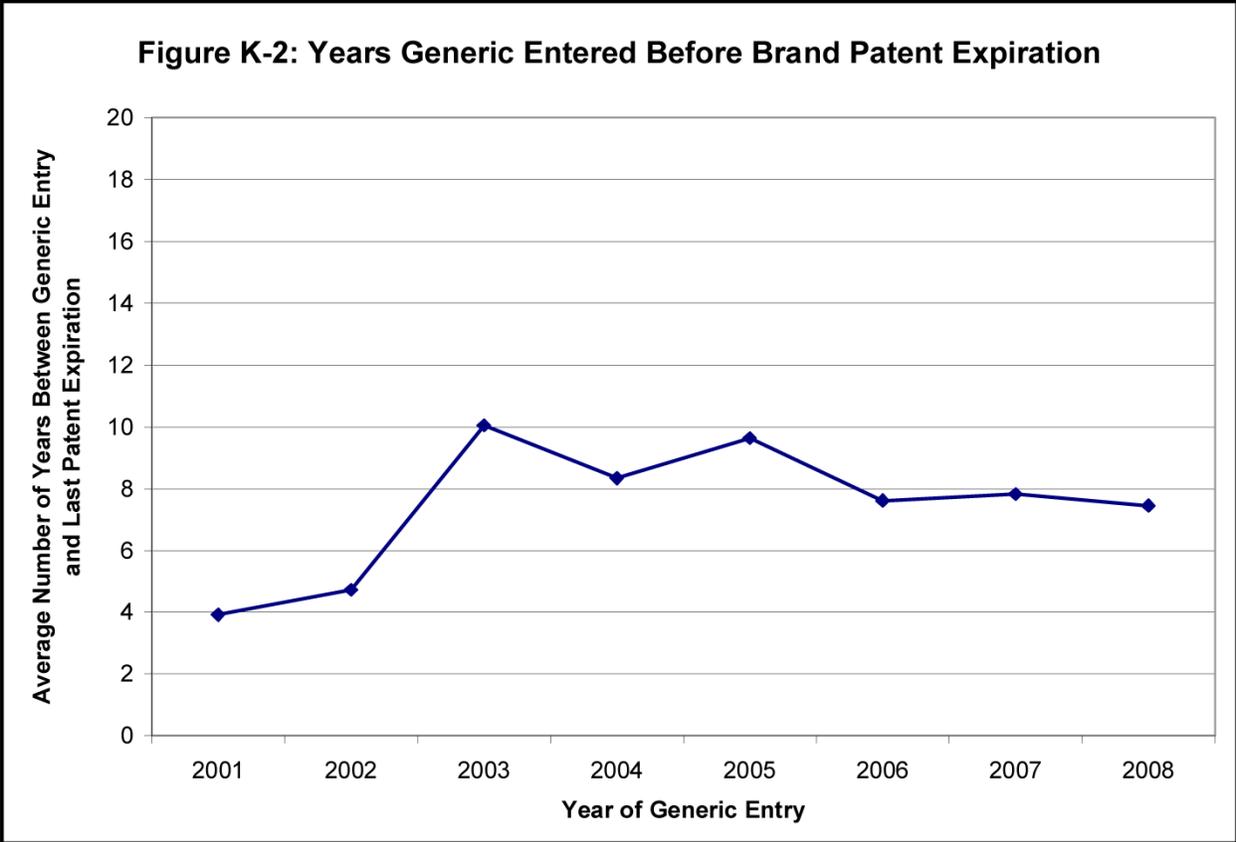
The foregoing overview of the US system should highlight at least one of its features. It is the best thing that ever happened to patent litigators and FDA regulatory lawyers. It is an extremely complex system that is largely impenetrable to all but a handful of legal and regulatory experts. It is expensive to participate in as a player. Yet, as a US citizen my assessment is not so critical, on the whole. Though there are problems, generic products enter the market in the USA promptly after patent expiration. And, there is substantial financial incentive to challenge the patents held by originators.

¹⁵ See, e.g., *In re Lipitor Antitrust Litig.*, 2014 U.S. Dist. LEXIS 127877 (D.N.J. 2014); *In re Effexor XR Antitrust Litig.*, 2014 U.S. Dist. LEXIS 142206 (D.N.J. 2014). Seth Silber, Jonathan Lutinski, & Ryan Maddock, "Good Luck" Post-Actavis: Current State of Play on "Pay-for-Delay" Settlements, CPI Antitrust Chronicle, Nov 2014 (2).

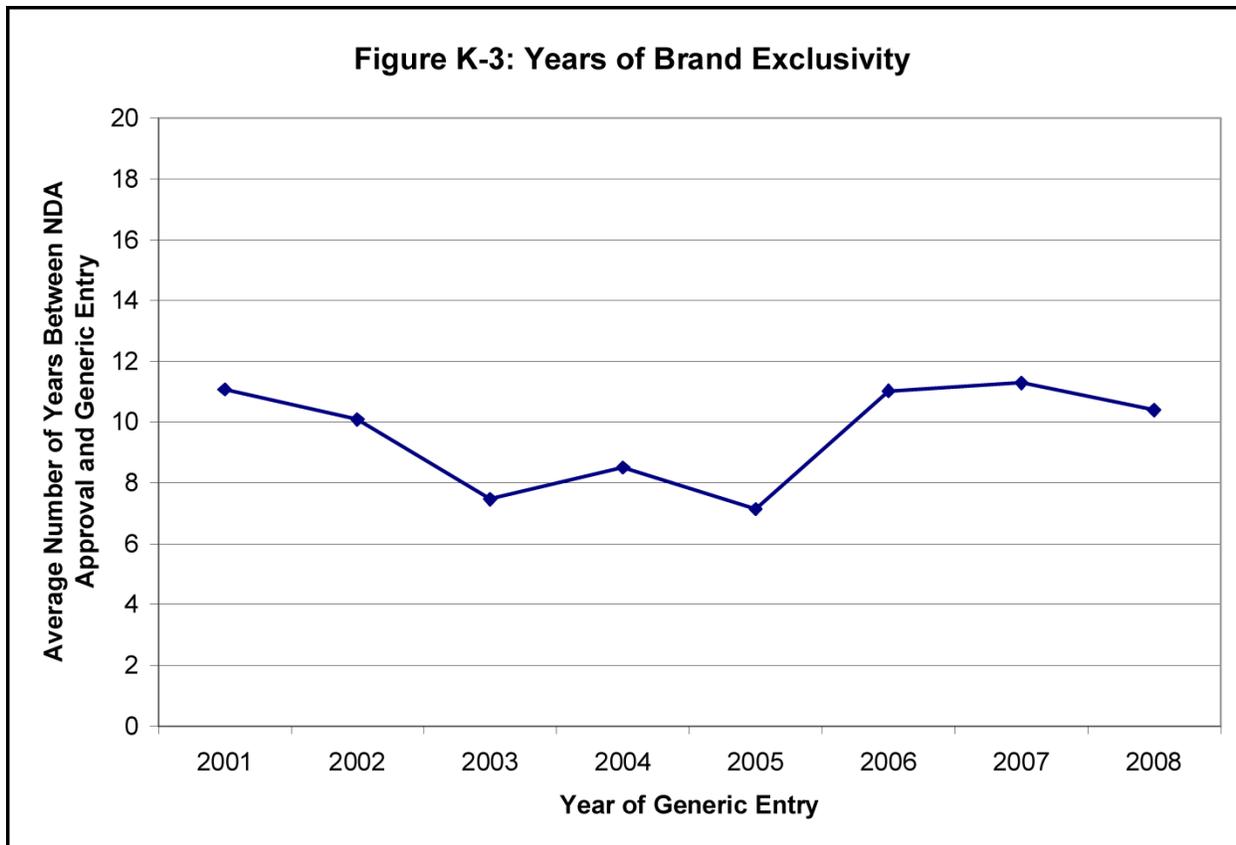
¹⁶ FTC Authorized Generics, at, e.g., vi-vii.



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



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



The main problem with the USA system as it is currently implemented is the very broad interpretation of patentable subject matter (including through interpretation of the criteria of patentability) applied by the US PTO and Court of Appeals for the Federal Circuit, allowing patenting of minor modifications, new dosages, patient populations, etc., which effectively permits patent flooding by the originator companies. That is not so much a question of the generic pathway, but of the scope of protection of pharmaceutical products by patent. This creates burdens on the pathway because it means that there are more patents that must be challenged, but that is not necessarily the same thing as a problem with the pathway design.

In terms of the generic pathway, it would be nice to simplify the system, but the development, testing and marketing of a new drug is inherently complex; patents are complex; and there is only so much simplification that can be done.

But, the USA system only works because of several critical factors.

First, there is a very significant financial incentive for generic producers to enter the USA market. This is based on a combination of factors, including the potential for securing a 180-day market exclusivity period, and more generally the high volume of potential generic sales in the US market. Generic producers are willing to pay lawyers and experts substantial sums of money (in the millions of dollars) to challenge the patents of the originators in court.

Second, there are governmental institutions, including the Federal Trade Commission, the Department of Justice, the State Attorneys General, and others that are paying attention to the pricing and practices of both the originators and the generic producers, and that are willing to intervene to make the system work for the benefit of the patient/consumers. This includes initiating actions under the antitrust (or competition) laws, as well as under the antifraud laws when these mechanisms are used to take unfair advantage of government drug reimbursement programs.

Third, there is a competent independent judiciary that referees the activity. While the tendency of the Court of Appeals for the Federal Circuit has been to support the interests of originators and to protect patents, the US Supreme Court over the past several years has intervened to control this over-protective tendency. The US courts have developed a sophisticated patent and health regulatory law jurisprudence that accounts for nuance. This entire judicial apparatus is expensive to operate.

Fourth, pharmaceutical prescription plan operators are increasingly sensitive to pricing issues and are encouraging use of generic products. While the originators continued to lobby for strong IP protection and high prices, there is a significant counter lobby involving consumer groups, state government health officials, and others constrained by budgetary limitations.

5. A model for the world?

The USA has incorporated elements of the US Patent Act and the Hatch-Waxman generic regulatory pathway in a number of bilateral and regional free trade agreements, including those negotiated with countries of Latin America. The specific elements have varied. Several of the elements initially incorporated in the FTAs with Colombia, Panama and Peru were modified in favor of the generic industry subsequent to the initial signing of the agreements based on US congressional intervention. The recent US-South Korea FTA, on the other hand, shows a strong form of USA demands regarding the pharmaceutical sector.

Draft provisions proposed by USTR in connection with the Trans-Pacific Partnership (TPP) negotiations appear intended to transpose the US patent and regulatory pathway into the law of its Pacific trading partners. On the subject matter patentability, USTR has proposed:

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)

This new provision not only would imply coverage for the many types of secondary patents granted by the US PTO, but it is specifically designed to reject the approach taken by the India Patent Act, section 3(d), requiring an enhancement in efficacy as a condition of approving new forms of the same substance.

The provisions proposed regarding the term of marketing exclusivity for new entities, and for follow-on approvals based on submission of clinical information, attempt to mirror the requirements of US law (although they are probably more generous to the patent/exclusivity owner than US law) (see USTR Proposal of September 2011). Just as under the Hatch-Waxman regulatory pathway, a system would be put in place so that patent holders would be notified and would have the opportunity to initiate infringement litigation prior to any regulatory approval, there would be an automatic stay put in place, and the patent holder would have the opportunity to request preliminary and permanent injunctions. The draft suggests that a successful generic challenger to a patent should receive a reward for doing so, and a footnote is dropped to cover the fact that US law provides a reward to multiple same day paragraph IV certifiers. USTR's proposal would require that originators seeking to take advantage of these protective provisions should request marketing approval within the host territory within some prescribed timeframe, and USTR has suggested that this is a major incentive for countries to adopt the proposals.

It is also useful to note that USTR has incorporated provisions regarding the Doha Declaration on the TRIPS Agreement and Public Health, but true to form it has revised the text of the Doha Declaration to reflect its preferred negotiating stance, rather than the actual text of the Declaration.

Let us assume for the sake of argument that the TPP required the parties to mirror the US Patent Act and the Hatch-Waxman Act (including the regulatory pathway) in their national laws. As I have previously suggested, there is almost certainly a problem with the expanded scope of pharmaceutical patent subject matter that is bound to lead to excessive patenting. Already today patent examiners in many developing countries are willing to accept determinations of patentability previously made by the US PTO and/or the European Patent Office (including under the PCT), and there is little reason to suspect that this would change with the introduction of patent law standards more compatible with those of the USA.

These patents can be used to block drug regulatory authorities from granting marketing approval to generic drugs, unless and until the patents are successfully challenged in court. Recall that because of the rule of independence of the international patent system, the invalidation of a patent in the USA would not invalidate the patent in another TPP party, and a determination of non-infringement in the USA would not be effective abroad. Essentially, the generic industry in each TPP party would be "on its own" in seeking to challenge patents. And, recall that the originator companies are prepared to invest millions of dollars in defending attempts to invalidate patents (or defending attempts to have them found not infringed).

I would suggest that adoption of a system such as that proposed by the TPP, modeled on the US Patent Act and Hatch-Waxman system, would operate heavily in favor of the originator pharmaceutical industry, and make it significantly more difficult for generic producers to enter national markets.

What would be the justification for this from the standpoint of parties to the TPP other than the USA? The argument from USTR and the originator industry is that this would increase profitability for the

originators, which in turn would invest more in R&D, which in turn would yield new and better medicines, which in turn would be supplied to those other parties.¹⁷

There is probably some truth in that line of argument. If the originator companies are more profitable they will probably invest more in R&D and that may lead to new and better medicines. (This does not require us to be naïve as to how pharmaceutical revenues are spent. Even taking into account wasteful practices, some money does find its way into actual R&D.) The question is whether from the standpoint of countries other than the United States the preferred way to enhance pharmaceutical R&D is to send money to the USA in the form of higher pharmaceutical prices paid to USA-based multinationals. It seems more likely that countries in Latin America might prefer to redirect R&D toward domestic institutions and industry, though this is not necessarily an easy process.

Adoption by countries of Latin America of the USA model will almost certainly result in delay to the introduction of generics in Latin America, which will impose a price on public health systems and consumers. Public health systems and consumers will absorb the cost.

A proposal to make the FTAs work better for trading partners of the USA would be to add a provision that to the effect that any patent invalidated (or found not infringed) in the country of the originator would be presumed to be invalid (or not infringed) in all countries party to the FTA. Though the details of such a system could take a variety of forms, the essential idea is to eliminate the requirement that generic producers in other FTA countries must replicate court proceedings to invalidate (or obtain determinations of non-infringement of) patents. Without such a provision, it is possible that products for which there are generic substitutes on the market in the USA will still be exclusively provided by originator patent holders in its FTA partners. This type of provision would challenge the traditional idea of independence of patents under the Paris Convention on the Protection of Industrial Property (Incorporated by reference in the WTO TRIPS Agreement), but it is consistent with the "extraterritorial" approach taken by the USA with respect to data exclusivity. In other words, FTA partners are not permitted to rely on regulatory approvals granted in the USA even if no regulatory data is submitted in their territories. However, one would need to be careful to avoid linking this to a provision that patents granted in the country of the originator would similarly be granted in the FTA partner.

If trading partners of the USA conclude it is in their better interest -- as the price of concluding a TPP -- to move toward US standards in respect to patents and regulatory exclusivity, it will be critical that they enhance their attention to implementation and enforcement of competition law. International rules allow a substantial degree of flexibility in the application of competition law, and there are public health-friendly approaches that can be used. In addition to reverse payment issues, there is the possibility to address excessive pricing, sham patent litigation and other restrictive practices that can be

¹⁷ This line of argument is clearly made in DOC Pricing and R&D, supra note 2.

used to inhibit competition. The United Nations Development Program (UNDP) has, for example, recently published a guide book in this area.¹⁸

In the end, whether one concludes that the generic pathway in the USA is a model for the world depends on one's worldview. The USA model works reasonably well for the USA, and reasonably well for its originator and generic industries. It should work for the mercantile benefit of the USA if it is adopted in other countries. It may provide some additional new drugs for introduction into other countries, assuming that R&D in the USA is successful. At the same time, it will slow down the introduction of generics.

¹⁸ Abbott, Frederick M. and Flynn, Sean M. and Correa, Carlos M. and Berger, Jonathan Michael and Nayak, Natasha, UNDP, *Using Competition Law to Promote Access to Health Technologies: A Guidebook for Low- and Middle-Income Countries* (May 19, 2014). United Nations Development Program (ed. F. M. Abbott)(2014) . Available at SSRN: <http://ssrn.com/abstract=2439416>.