




Generic competition: USA experience and lessons for Europe

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24/10/2005

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This work reflects the author's views only, and not those of the US CFTC, nor any of its commissioners.

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- The economic concept of quasi-rent refers to a payment above that required to keep an asset in its current use.
 - In the pharmaceutical context, quasi-rents are the returns to R&D.



Policy Issues

- Quasi-rent can be large for branded drugs - for drugs currently on the market and protected by patents, production/distribution cost is often a small % of the price.
- This implies there is considerable scope for gov'ts to lower prices without inducing exit.




Governments face a trade-off

- Policies that result in lower prices benefit consumers and increase welfare in the short term (static gain).
- Pharmaceutical companies makes investments in the hopes of future quasi-rents.
- It follows that a reduction in future quasi-rents will lead to lower current investment, and hence fewer future drugs, harming consumers (dynamic loss).




Quasi-rents and generic competition

- Determining the magnitude of these off-setting welfare effects for innovator drugs has been challenging for economists and policy-makers.
- Lots of studies (e.g., Vernon, 2003, CBO, 1998), have attempted to estimate these trade-offs
- One advantage of studying generic drugs is that while the same basic trade-off exists, one has a better chance to accurately estimate the relevant magnitudes.



The trade-off between dynamic and static effects of policies is present for generic drugs in the following sense:


- Like branded drug companies, generic drugs companies have to invest to gain FDA approval (ANDA), in the hopes of making money down the road.
- If the rules change between the time they apply for the ANDA and the time it is awarded, resulting in lower prices, the rule change is not likely to induce exit.
- Hence, if the rules change so as to lower generic prices, it may not affect the number of generic competitors in the short term.
- In the short run, the new rule can lower prices, without affecting the number of generic competitors. However, if the new rules are known in advance, they will affect entry decisions. This in turn may lead to fewer competitors, and reduce or eliminate the beneficial effect of the new rule.

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- Advantages of generic market in examining trade-off
 - Less uncertainty about approval
 - Shorter time lag between beginning “research” and gaining approval.
 - Process more comparable across drugs.
 - Hence, a cleaner relationship between the incentive to enter and outcome than for branded drugs.



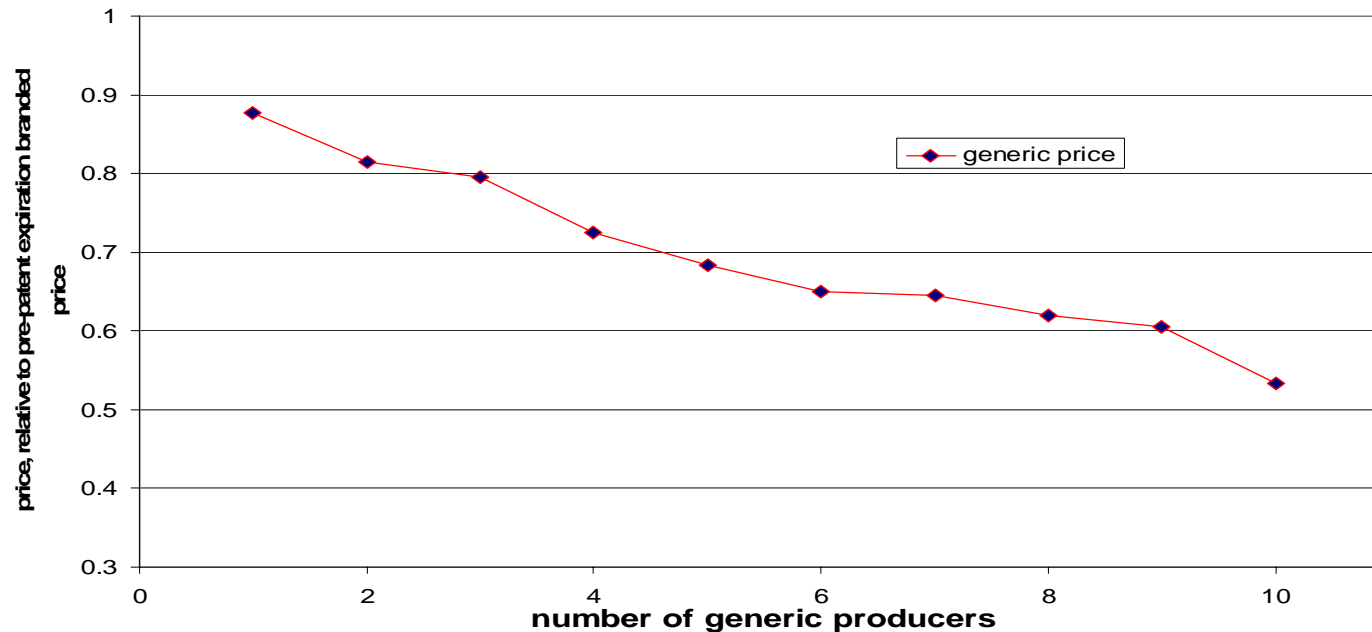
Features of Generic Drugs in the U.S.

- Although we are largely interested in generic drugs because of what they tell us about the trade-off between dynamic and static welfare issues, they are important in their own right, as well.
- In the U.S., more than $\frac{1}{2}$ of all prescription are filled by generics. The share has been increasing since the mid 1980s, when it was less than 20%.
- Given the size of the price difference between generics and branded drugs, the existence of a generic segment has a huge effect on drug expenditures in the U.S.

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- Mike Ward and I (2005) estimated the structural relationships that described entry and competition in generic drug markets
 - 1. Relationship between Price and the Number of Competitors

- The Number of Generic Competitors Affects Generic Prices

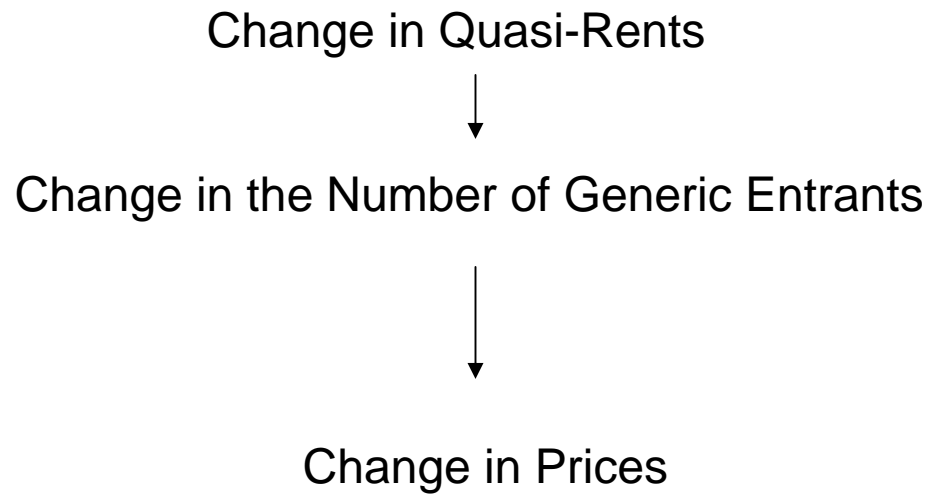
Relationship between generic prices and the number of generic competitors



2. Relationship between the size of the quasi-rents and the entry decisions of firms

- We find that drugs with greater sales revenues will yield higher profits to generic entrants, and hence more generic firms will enter.
- For example, other things equal, a drug that had monthly US revenues of about \$12 mil (in current \$) would have about 5 entrants after one year, while a drug with monthly US revenues of \$33 mil would have about 8.
- This provides a direct measure of how quasi-rents affect entry.

Use of Structural Model






Example - Effect of Alternative Government Policies

- Early 1990s – discovery that some generic firms had obtained FDA approval fraudulently. In response, the FDA increases their scrutiny, making the process more expensive.
- This raised application costs by about 50% during the post-scandal period, which reduced the number of firms applying for FDA approval.
- For the average drug in our sample, the expected number of entrants fell from about 9 to about 6, which led to a 5% increase in generic prices.



Strategic Behavior by Incumbents

- The branded pharmaceutical companies want to limit the effects of generic competition.
- For example, for a large revenue drug, an additional year of patent protection can increase the incumbent's profits by more than \$100 mil.



In the US, we have observed a variety of tactics by the branded firms to reduce the effect of generic competition.

- introducing a new version of the product with somewhat different features (e.g., one-per-day dosing), thereby shifting some consumers from the drug whose patent will soon expire.
- introducing “process” patents on the old drug, making entry more difficult.
- “Para IV” Settlements
- “Submarine” Patents
- Branded or “Authorized” Generics



Branded Generics

- The branded firm introduces its own generic just prior to patent expiration, or alternatively, contracts with a generic firm to do that.
- This means that the patent holder becomes the first generic entrant.
- Since our estimate indicates that the first generic entrant earns a disproportionate share of the total quasi-rents, this can have a large effect on the expected quasi-rents.
- This in turn leads to a reduction in the number of independent generic entrants of more than 1.

We are worried that a small, independent company will not risk hundreds of thousands of dollars and years of effort to receive an ANDA [i.e., FDA] approval and introduce a product into a market already controlled by fully distributed PMA's [i.e., innovator drug companies] generic version of its own branded product. Without that competition, generic drug prices would not achieve the affordability that is offered today.

Morton H. Katz,

Chairman of the National Association of

Pharmaceutical Manufacturers (representing

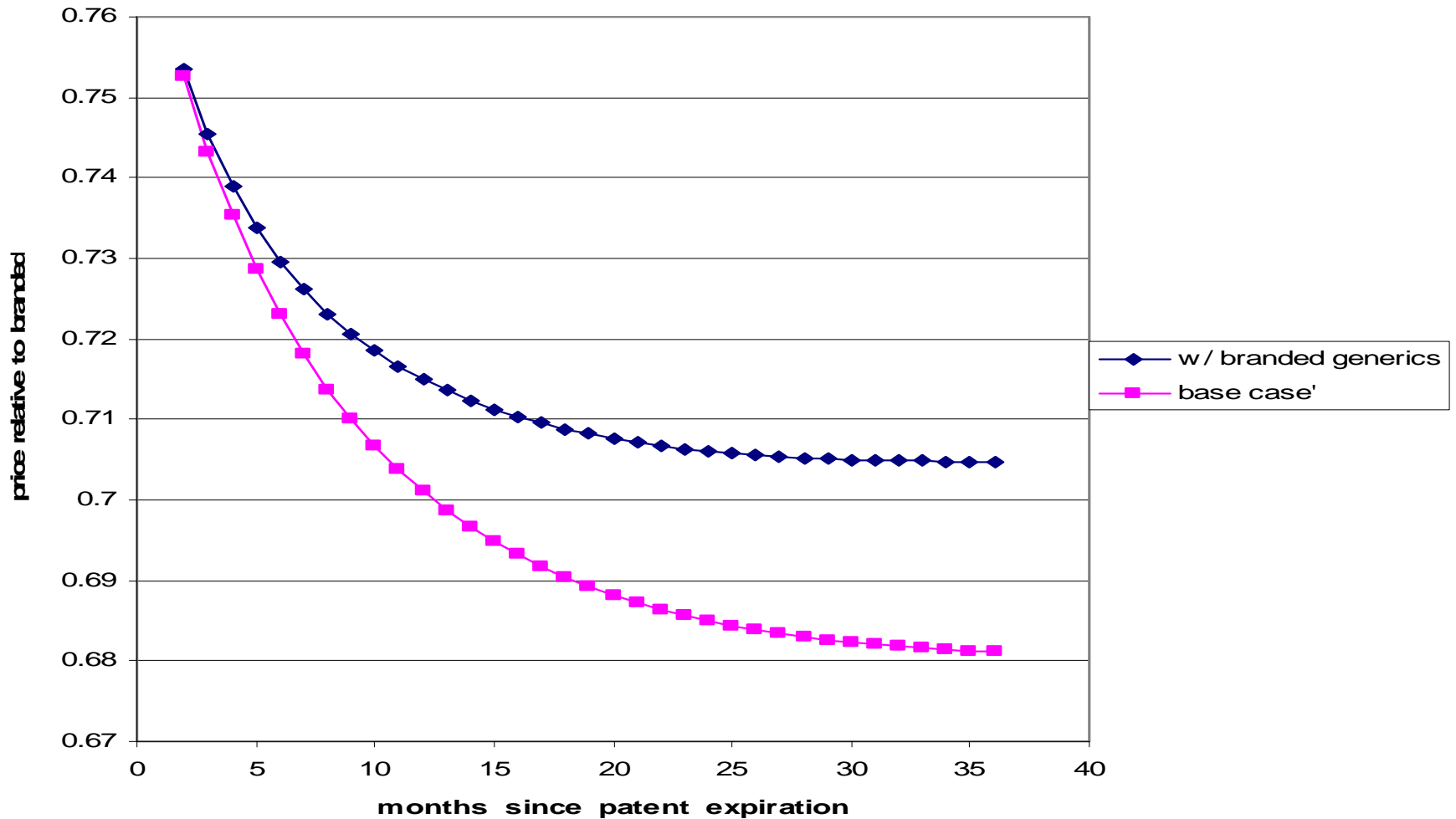
generics producers)



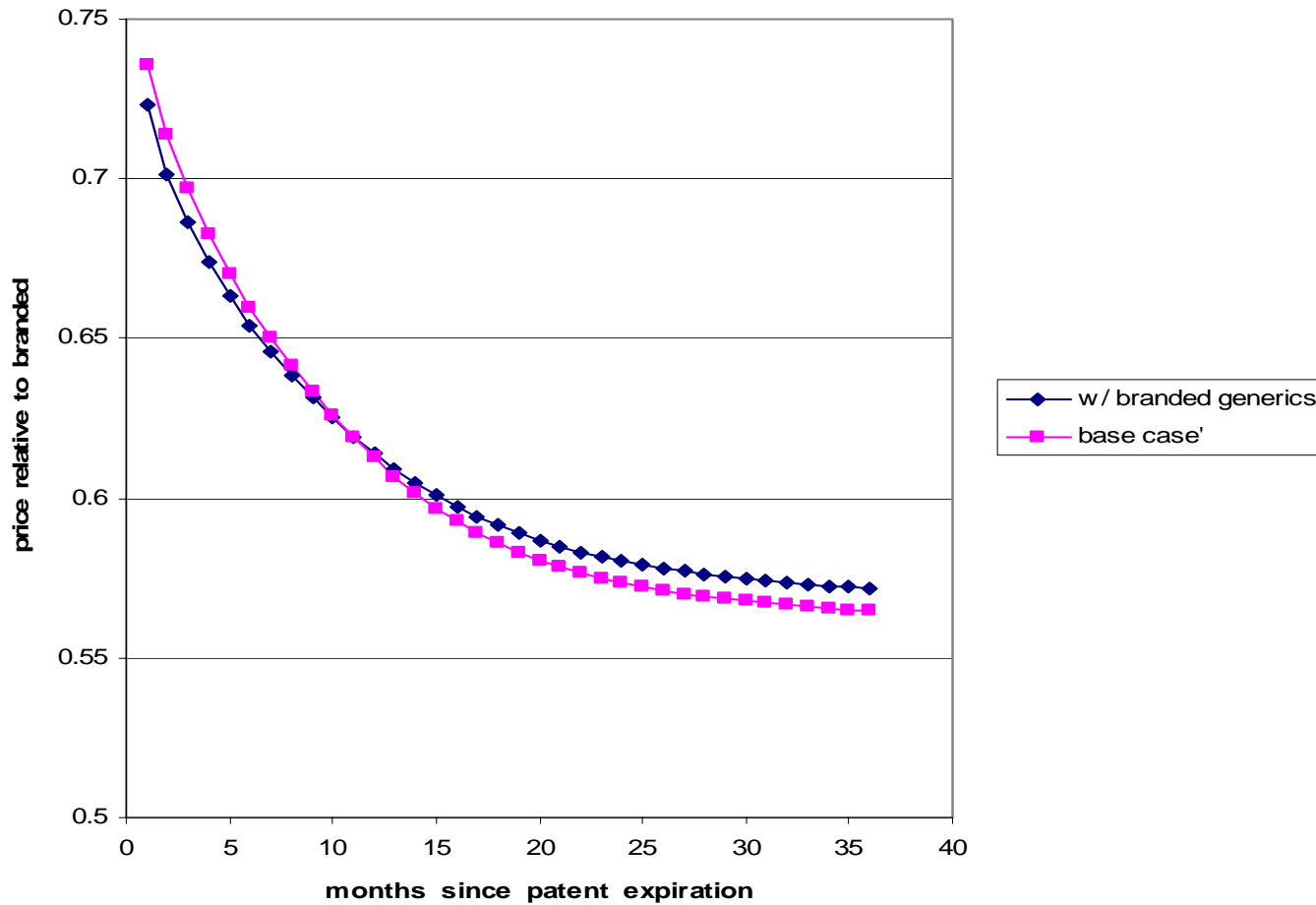
Estimated Effects

- We estimate that for the average drug in our sample, the branded or authorized generic reduces the number of independent generics by between 2 and 3, leading to a small increase in generic price (about 1.5%).
- Tends to have largest effects for small-revenue drugs.

Effect of Branded Generic Entry for Small Revenue Drugs



Effect of Branded Generic Entry for Large Revenue Drugs



Conclusions

- The big issues in pharma policy result from the fact that gov'ts have a trade-off in determining how pharmaceutical companies will get compensated.
- Our studies show that even in generic markets, where entry costs and risks are relatively small, there are still effects of changing the costs and benefits to firms of their R&D.
- The same is likely going on in markets for new drugs. And since innovation in new drugs is likely more important than additional generic firms, it is important to recognize this trade-off.