Competition, Market Power and Pricing in Brand Name Pharmaceutical Markets

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Branded pharmaceutical innovation has been declining substantially for over 60 years. Drug innovation is dependent on sufficiently high prices and profits to reward risky and costly R&D. In assessing competition in pharmaceutical markets government agencies evaluating potentially anti-competitive behavior can misapply pricing tools developed elsewhere. In other industries measures of cross-price elasticity of demand are crucial for assessing relevant economic markets, but since branded pharmaceuticals often don't compete on price, these measures lose relevance. Rather than focusing on drug pricing behavior, assessments of anti-competitive conduct in branded pharmaceutical markets should reflect the distinct institutional characteristics of these markets.

Eroom's Law: Brand Name Drug Innovation and Pricing

Pharmaceutical innovation is highly risky, slow and costly. The average costs of bringing a new drug to market exceeds a billion dollars, and the average development time exceeds a decade.[1] Over the past six decades there has been an alarming and relentless decline in pharmaceutical research productivity, with the number of new US Food and Drug Administration (FDA)-approved drugs per inflation-adjusted billion dollars of R&D spending dropping in half about every nine years since 1950. This is an industry problem so serious that it has been characterized as Moore's Law in reverse, or "Eroom's Law."[2] While the causes of this decline are complex and not fully understood, it is clear that lower branded pharmaceutical prices and profits will only compound the problem.

Brand name drug manufacturers are typically granted patent protection or other forms of market exclusivity specifically to encourage and reward them for bringing innovative treatments to market.[3] This means that manufacturers can set prices for their branded pharmaceuticals. Branded drugs sell at market prices that are often many times higher than the marginal cost of production. This is not, by itself, evidence that the manufacturer possesses market or monopoly power in the sense that government agencies like the U.S. Department of Justice (DOJ) or the Federal Trade Commission (FTC) use these concepts to gauge illegal anti-competitive or monopolistic market behavior. Typically these prices reflect the legally-sanctioned market-exclusivity reward for innovation.

Brand name drug manufacturers compete fiercely in research and development of new experimental pipeline products, and in the acquisition of new products from other organizations (including academic institutions, other biopharmaceutical companies, and the National Institutes of Health). They also compete in re-positioning their products with post-approval R&D studies. They devote substantial effort to the marketing and promotion of their brands, since they only have a limited time of market exclusivity before bioequivalent generics can enter the market and wipe out their profits. Prices are often only a minor dimension of branded drug competition.

Branded Drugs Typically Don't Compete on Price

In various legal cases government agencies and some economists have proposed a theory of drug price competition that may well apply to other markets, but is totally alien to how branded pharmaceuticals compete. Under this theory competing branded drugs could enhance their market shares with aggressive price discounting. As a result the prices for branded drugs should drop substantially as each company competes away excess profits to gain sales. Contrary evidence of sticky drug prices or price hikes in the face of competitive challenges would be prima facie evidence of anti-competitive market conduct under this view. However, branded drugs compete primarily on their perceived and actual clinical attributes, not their prices.[4,5,6] This is particularly the case when the drugs are used in life-threatening situations, or when drug choice can lead to fatal or permanent health consequences.

If a doctor makes the wrong choice on a drug to treat minor heartburn, the patient may experience some short-term discomfort but typically the worst outcome will be a return visit to the doctor to switch to an alternative medication. For life-threatening conditions such as HIV/AIDS, metastatic cancer, myocardial infarction or end-stage COPD the wrong medication choice could lead to progressive disease, irreversible patient health deterioration, or even death. The last thing on the doctor's mind in those situations is saving a few dollars by using Drug A rather than Drug B. They will choose the drug that they personally believe is the most likely to produce the best clinical outcomes for their patients. This is especially true when, as is typical for such patients, neither the physician, nor the patient nor the patient's family bear any of the differences in drug prices because of health insurance or government health care program coverage.

In this regard it makes little difference whether there is consensus in the clinical literature about which drug is actually better. Even if there were clear clinical evidence that Drug A is superior, no price discount would be sufficient to get doctors to choose Drug B. Conversely, if the clinical evidence favors Drug B, than no doctor would choose Drug A, regardless of its price. American doctors are trained to save lives, not dollars.

If, as is often the case, there are no definitive studies showing superiority for Drug A or Drug B, clinicians will band into alternative treatment camps. Absent clear findings from a head-to-head comparative effectiveness trial of A versus B, clinicians using treatments with potentially fatal or serious health consequences are not going to alter their prescribing in response to drug price changes. Considered from a cognitive dissonance perspective,[7] it is perfectly natural that a doctor who routinely makes life-saving decisions will have strong idiosyncratic treatment preferences precisely in those situations where the clinical evidence is ambivalent. It would be hard for doctors to live with themselves thinking that all the patients they'd treated with Drug A (including some who have died) would have actually done better with Drug B. It's inconceivable that well-meaning doctors would alter these critical decisions based on relative drug prices, whether the clinical evidence is ambiguous or not.

Moreover, in most cases drug companies selling FDA-approved medications are unlikely to risk their existing market shares by conducting head-to-head clinical trials to test whether their drugs are actually superior to their competitors. This has been tried a couple of times with high-profile negative consequences for the sponsoring manufacturer, such as when Bristol-Meyers Squibb ran a trial of their drug, Pravachol, against the leading statin, Lipitor and lost in the PROVE-IT trial.[8] Similarly, Merck's ENHANCE trial found their drug Vytorin to be no better than generic simvastatin.[9] An easy path to unemployment for a pharmaceutical executive is to conduct a clinical trial against their competitors and lose. This private market failure to provide socially-valuable drug information is one reason why the Patient-Centered Outcomes Research Institute (PCORI.org) was established under the Affordable Care Act.[10]

If the SSNIP Don't Fit You Must Acquit

Government agencies routinely evaluate in-

dustry conduct and enforce anti-competition laws. To assess whether a company has market power subject to potential abuse one first has to determine which products compete against each other in the relevant market. As described in the DOJ and FTC Merger Guidelines, relevant economic markets are typically identified using the "SSNIP" (small but significant and non-transitory increase in price) test.[11] This means that if a small price increase (e.g., 5-10%) for Product A cannot be permanently sustained without losing customers and net revenue to Product B, then Product A and Product B are in the same relevant economic market. Yet often, as with the famous glove in the OJ Simpson trial, applying the 'square peg' theory of SSNIP test pricing conduct to the 'round hole' of pharmaceutical products to assess relevant economic markets simply doesn't fit. When brand name pharmaceutical products don't compete on price, demand elasticity estimates and SSNIP tests typically aren't very useful in assessing market conduct.

Branded drugs routinely sustain their sales volumes despite significant price increases. Naïve application of the SSNIP test to pharmaceuticals could imply nonsensical conclusions such as every brand name drug is alone in its own relevant market without competitors. For example, application of the SSNIP test could lead to the conclusion that generic bioequivalently identical versions of a branded drug are not in the same relevant economic market, since the branded drug can raise its price by more than 5% and yet lose no further customers to the generic competitors after the initial brand defections.[12]

What happens in situations for life-saving drugs (e.g., for cancer, HIV/AIDS, congestive heart failure, cystic fibrosis, etc.) is that the demand curves are so inelastic that small permanent price changes are irrelevant to physician prescribing decisions. In these circumstances drug prices are not constrained by economic market forces, but rather by external political and social pressures. The manufacturer of life-saving drugs can often increase revenue by charging substantially more than they actually do and get away with it in the market, but possibly not in the political or public relations arenas. It is possible that at some much higher price than they actually charge the SSNIP test would show some cross-price demand elasticity. In fact, oncology and other specialty drug manufacturers now routinely charge $10,000 to $250,000 per patient for new drugs that add only a few months of life.[13,14] Only at these stratospheric specialty drug prices are we starting to see some nascent price sensitivity.[15]

To assess anti-competitive conduct in branded pharmaceutical markets, rather than SSNIP tests, the FTC and other government antitrust agencies should be using nontraditional tools that reflect the institutional realities of the pharmaceutical marketplace. They should carefully consider how corporate conduct would differ under alternative hypothetical drug divestiture scenarios. The best evidence on this will generally not be based on econometric demand estimates. It will include evidence from clinical researchers, physicians, pharmacists, third party payers, drug company officials and others to define relevant markets and assess product substitutability along with real-world and hypothetical "but for" market behavior.

Branded drugs inevitably will be perceived to have some level of market power precisely because drug patents are granted to encourage and reward drug product innovation by allowing prices to exceed marginal cost. Society needs to balance goals of efficient competitive markets against goals of ensuring that pharmaceutical manufacturers are rewarded to keep innovating. It is certainly hypothetically possible for a branded pharmaceutical company to achieve dangerous monopoly power and engage in harmful anti-competitive behavior. But pricing patterns alone are insufficient to assess this behavior.

Pricing conduct is often a red herring in assessing pharmaceutical market conduct. Nonetheless it can make the media headlines and Senate floor speeches. In many cases drug manufacturers are so sensitive to the political blowback that they set branded drug prices well below levels that can be justified on the basis of actual drug value. This may be one of the reasons why drug innovation has been declining for decades. In any case, drug prices should not trigger antitrust litigation unless tangible anti-competitive market conduct is occurring. Rather than focusing exclusively on pricing behavior, we should look for such conduct in all possible dimensions of drug company behavior including: engagement in clinical research, product promotion and marketing, product quality and innovation, customer satisfaction and barriers to competitor market entry.

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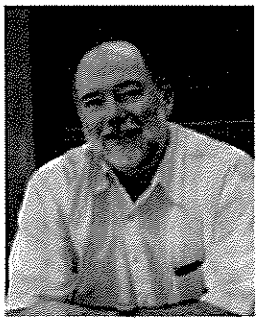

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