

***Schering-Plough* and the FTC's Unusable "Direct Test" of Monopoly Power in Pharmaceutical Markets**



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FTC vs. Schering-Plough, et al.:

Background



- Schering held a patent on a micro-encapsulated extended-release potassium chloride supplement which it marketed in the U.S. as K-Dur 20.
- In late 1995, Upsher Smith, a generic drug manufacturer, applied for FDA approval to market a generic version of the product.
- Schering sued for patent infringement and, after protracted litigation, the parties agreed to a settlement in June 1997.
- Under the settlement, Upsher was permitted to enter the market no earlier than September 2001 (the patent will expire in 2006) and Schering licensed several other Upsher products in development (products unrelated to potassium chloride), for which it agreed to pay \$60 million.
- The FTC declared that the licenses to other Upsher products were a sham, and that the \$60 million payment nothing more than a bribe that Schering paid Upsher to delay its entry into the marketplace.
- The FTC further proposed a “direct test” for monopoly power that it applied to this case. According to this test, Schering’s K-Dur 20 possessed monopoly power which was preserved by the Upsher agreement.
- Procedural history.

The FTC's "Price Test" for Monopoly Power



- Ordinarily, testing whether an agreement is anti-competitive under the rule of reason involves evaluating whether monopoly power is present to begin with (the monopoly power screen).
- This usually involves defining a relevant market and then assessing conditions within that market. However, the FTC eschewed that approach in this case.
- The FTC urged a so-called “direct test” for monopoly power: if an entrant can take substantial sales from the incumbent and the average market price falls significantly after entry, the incumbent must have possessed monopoly power prior to the entry.
- This proposed test has intuitive appeal, but its application to the world of pharmaceuticals is fraught with difficulties. In fact, in pharmaceutical markets, this test is unusable.
- That is because it entirely overlooks the institutional characteristics of the pharmaceutical industry in general, and of the nature of competition from “AB-Rated Generics” in particular.

Two Polar Cases of Branded Pharmaceutical Products



- Consider a branded drug that confers genuine therapeutic advantages over any existing formulation; these advantages could support a premium price for that drug.
- Once the manufacturer has made medical practitioners aware of these advantages, the drug's therapeutic benefits will sustain the price premium as long as no equivalent substitute product is available.
- Under these conditions a branded drug could have monopoly power. (Although the inquiry would not stop there).
- Now consider the very different case of a branded drug that confers no material therapeutic benefit over existing alternatives. Rather, the patent underlying the drug covers an alternative (technically unique) delivery mechanism.
- This delivery mechanism can be exploited, let us say, by creative marketing and brand-building activities. In that event, any price premium that the branded manufacturer can extract depends entirely upon the brand awareness created by its advertising and marketing efforts.
- This is no different from the branded loaf of white bread being more expensive than most private labels, even if the private label loaf is equal or even greater in objective quality.
- This premium has nothing whatsoever to do with monopoly power. It is merely the economic return to the advertising, promotional and other brand-building efforts undertaken by the manufacturer.

The FTC Test Cannot Distinguish these Polar Cases



- Because of the unique institutional nature of AB-rated generic competition, the effects of generic entry will be similar enough that the FTC test will not be able to distinguish these two cases.
- In the first case, of the drug that confers true therapeutic benefits, physicians will continue to prescribe the drug, because of these benefits (as long as there are no other branded substitutes available). Mandatory and permissive substitution laws will ensure that (a) the generic will be dispensed in place of the brand; and (b) that the average price paid will fall as a result.
- In the second case, too, any prescriptions that are written for the branded drug will be filled with the generic, again resulting in reduced average prices.
- The FTC test will yield the same answer in both cases—both branded drugs will be found to possess monopoly power.
- However, the output effects—frequently a much better measure than price—can be very different in the two cases. Direct output (of pills or doses) as well as related output such as informational advertising, may actually drop in the second case.
- The FTC's test simply proves too much: all branded pharmaceuticals will be found to have monopoly power under this test.

The Existence of Firms Uniquely Qualified to Compete Does Not Necessarily Indicate Monopoly Power



- The problems with the FTC's test are a special case of a more general problem: the fact that entry by a particular firm may reduce prices does not necessarily indicate monopoly power for the incumbent, if the particular entrant is uniquely able to compete with the incumbent.
- Theft of trade dress can create a competitor uniquely able to compete with the original owner to the benefit of its customers. That does not mean that the original owner had monopoly power.
- Covenants not to compete are commonplace; their violation frequently could result in short-term benefit to the customers affected by the covenant. Again, this does not indicate that monopoly power was present.

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