Economics at the FTC: Pharmaceutical Patent Dispute Settlements and Behavioral Economics

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Abstract:
Economics at the Federal Trade Commission (FTC) supports both the competition and consumer protection missions of the agency. In this year's essay we discuss two issues, one from each of the agency's missions. First, we focus on intellectual property issues in pharmaceuticals. Specifically, we discuss the principal rationale for antitrust concerns about certain patent dispute settlements in the ethical drug industry. Then, we discuss consumer economics, our recent behavioral economics conference, and how behavioral economics influences our thinking about consumer policy.

Keywords: Antitrust, Behavioral economics, Consumer protection, FTC, Patents, Pharmaceuticals

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generated by private equity buyers, such as the Blackstone Group and Kohlberg Kravis Roberts & Co. (KKR), purchasing assets and taking firms private. Only in exceptional cases does that type of purchase lead to potentially interesting antitrust issues. Still, the amount of purchase and divestiture activity by "strategic purchasers" (i.e., related firms in the market) has been sufficient to keep the FTC busy. We reviewed 28 mergers in great depth last year, and the agency challenged all or some aspect of 16 of those transactions. To help make sure that such challenges are good policy choices, we continue to look back at a subset of previous FTC merger actions to evaluate their effects.

Although mergers typically command the bulk of our attention on the antitrust side of the FTC, we have been occupied in recent years with a non-merger antitrust issue – whether the settlement of patent disputes in the pharmaceutical industry might lead to enhanced market power beyond that legitimately conferred by patent rights. It is to that subject that we now turn.

2 Exclusion Payments in the Settlement of Pharmaceutical Patent

The FTC's concerns regarding patent litigation settlements in the pharmaceutical industry began to develop in the late 1990s. These concerns resulted in several investigations and enforcement actions. An especially noteworthy investigation examined two settlement agreements between Schering-Plough and, respectively, Upsher-Smith and ESI, a division of American Home Products (AHP).[1] These agreements concerned Upsher-Smith's and ESI's generic versions of Schering-Plough's K-Dur extended-release potassium chloride supplement. Both generic companies agreed to give up all rights to sell their generic versions of K-Dur before the entry dates specified in their respective agreements, and both received monetary compensation from Schering-Plough. In March 2001 the FTC issued a complaint against all three companies. At issue in this case was whether Schering's payments to Upsher-Smith and ESI compensated them for delaying the onset of generic competition, to the detriment of consumers. In December 2003 the Commission issued its final decision in the case, unanimously concluding that the agreements had harmed consumers.[2] ESI had previously settled its case by accepting a Consent Decree,[3] but Schering and Upsher-Smith appealed to the 11th Circuit Court of Appeals, which reversed the FTC's decision in March 2005. The Commission appealed the 11th Circuit's decision to the Supreme Court, which declined to grant a writ of *certiorari*, thus ending the case.

The *Schering* case and others like it raise important economic questions, including the nature of the welfare standard that should be used to evaluate patent litigation settlements and whether there should be formal restrictions on the kinds of settlements that branded and generic pharmaceutical firms can reach. In this section, we develop a simple model to expose some of the economic issues that arise in the evaluation of these agreements, and we describe some

[1] See http://www.ftc.gov/os/2001/04/scheringpart3cmp.pdf for the Commission's complaint in the Schering case.

For related examples in the pharmaceutical industry, seesps0.0505 Tclcv-5(e 5(e 5Couum)11Tooa,24vt 0 Tc 6.d 0.Dw 22.066 9t)8esps

characteristics of the pharmaceutical patent settlements that the FTC has examined in recent years.

2.2 Regulatory Environment

The pharmaceutical patent litigation settlements that have attracted the FTC's attention have arisen in the regulatory environment that Congress created by the passage of the Hatch-Waxman Act in 1984.[4] This law created a mechanism for approval of generic versions of branded pharmaceuticals. A firm seeking approval of a generic version of a branded drug must file an Abbreviated New Drug Application (ANDA) with the Food and Drug Administration (FDA). In order to obtain approval of its generic product, a firm must demonstrate through its ANDA that the generic product is therapeutically equivalent to the branded product, which means that it has the same active ingredient, form, dosage, strength, and safety and efficacy profile as the branded product. The generic version must also be "bioequivalent" to the associated branded product. Two drugs are bioequivalent if they are absorbed into the body at approximately the same rate.

After concluding that a generic drug is therapeutically equivalent and bioequivalent to a branded drug, the FDA denotes the generic drug as AB-rated to the brand-name drug.[5] Pharmacists are generally able to substitute an AB-rated generic drug for the corresponding branded version without obtaining the approval of a customer's physician.[6] This substitutability between the branded product and the corresponding AB-rated generics plays a critical role in the competitive effect that generic drugs create.

When a generic firm files an ANDA, it must make a certification regarding any patents that cover the corresponding branded product. The branded drug's manufacturer lists these patents in an

[4] This law is formally known as the Drug Price Competition and Patent Restoration Act of 1984, Pub. L. No 98-417, 98 Stat. 1585 (1984).

[5] See Federal Trade Commission (2002) for a more detailed description of the generic approval process.

[6] Pharmacists have not always had the ability to substitute a generic product for its branded counterpart without physician approval. Through its advocacy, the FTC played a role in states' adoption of substitution laws that gave pharmacists this power. See Masson and Steiner (1985) for a discussion.

FDA publication called the “Orange Book.” In the context that we are considering, the relevant certification is a “Paragraph IV” certification, by which the generic firm claims that the patent or patents listed in the Orange Book are either invalid or will not be infringed by the generic product. If the branded firm files an infringement suit within a 45-day time frame following such a certification, the FDA cannot approve the generic product for at least 30 months, or until either the patent expires or the lawsuit is adjudicated, whichever period is shorter. This delay in the generic product’s FDA approval was designed to provide a period during which any patent litigation can be resolved.

One of the key provisions of the Hatch-Waxman framework is the grant of 180 days of marketing exclusivity to the first generic manufacturer that files a Paragraph IV ANDA. During this period the FDA may not approve subsequent ANDAs for the same drug product. The rationale for this prize is that it will encourage generic firms to challenge weak or narrow patents. In practice, this provision may have sometimes enabled the branded company to prevent entry of a queue of entrants by settling with (and delaying the entry of) the first filer. Until the first filer’s exclusivity has either lapsed or been forfeited, the FDA cannot grant final approval to the subsequent filers.

The Hatch-Waxman regulatory apparatus likely influences the bargaining that takes place between the incumbent patent holder and the generic entrant. In addition to the effect of the 180-day exclusivity noted above, the ANDA filing requirement provides the branded drug’s manufacturer with information about the number and identity of the firms that seek to enter with their own generic versions. Without this filing requirement, the branded drug manufacturer would not necessarily be aware of the existence of an entrant until that firm offered its product for sale. Under Hatch-Waxman, however, an incumbent can settle with an entrant with some certainty about how competition could potentially evolve, at least over a 30-month time frame. Furthermore, Hatch-Waxman allows for an opportunity to resolve the patent infringement issues before the generic has started marketing its product. Thus, the parties may be able to resolve any dispute before there are damages. In a typical patent infringement case, where the suit occurs after marketing has started, the settlement would need to address the issue of any potential damages that have already accrued.

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month of delay suggests that there are gains from trade between the two firms.[10] In Figure 2 we illustrate the regions of settlements – involving both an entry date and a payment of cash to the entrant – that the parties prefer to a particular settlement that includes only an entry date. The curves $U^B(1)$ and $U^G(1)$ represent iso-profit curves of, respectively, the branded (B) and generic (G) firms that identify the sets of settlements that leave each as well off as the settlement labeled 1. Both firms prefer settlements in the shaded region to 1.[11] Absent any constraint on their ability to reach such a deal, the parties would have a powerful incentive to delay generic entry, since doing so would increase

alternative, and that also includes compensation from the branded company to the generic company.[12] In this simple model, such a settlement exists if there are positive litigation costs that the parties can save by resolving their dispute before a trial. These costs explain why the branded firm's reservation entry date for a settlement that does not include a cash payment, labeled in the Figure as t_B, is earlier than the five-year mark. Suppose that antitrust enforcers could establish only that the generic entrant's probability of winning the patent case was between 30 and 70 percent, implying that consumers would have received between three and seven years of expected competition in the event of litigation. If the

the branded firm could overpay for something that it acquires from the generic firm, or the generic firm could underpay for something that it acquires from the branded firm.

In the FTC's *Schering* case, the evidence demonstrated that Schering-Plough had both paid $60 million directly to the generic firm Upsher-Smith and received rights to several

firm demands, thus preventing settlement. In this model, the payment of net consideration can enable settlement because it enables the incumbent firm to signal its private information. Intuitively, an incumbent that knows that the patent has a long economic life is willing to pay more to secure a late entry date than would be the case if it knew that the patent had a short economic life.

It is clear that there are situations where the payment of net consideration from the incumbent branded firm to the potential generic entrant would facilitate settlement. Yet one might question whether any of those settlements would be worth having. While there theoretically may exist consumer-friendly settlements that include both a payment from the incumbent to the generic entrant and a delayed entry date for the generic firm, there may be little chance that the firms would actually choose one of these, especially given the practical difficulties that antitrust enforcers face when developing evidence in these cases. Antitrust enforcement might therefore be relatively ineffective at preventing harm to consumers from these sorts of patent litigation settlements.

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preceded the disclosure of the FTC's interest in these agreements; it ended in late 1999. The second period, characterized by relatively strong antitrust enforcement, ran from late 1999 until March 2005, when the 11th Circuit reversed the Commission's decision in the *Schering* case. During this time, the FTC was actively investigating numerous settlement agreements involving many different firms, and the Commission's decision in the *Schering* case had taken the position that a patent litigation settlement was likely to be harmful to consumers if it included both compensation to the generic entrant and a future entry date. The third period, characterized by a relaxation of antitrust constraints on patent litigation settlements, began in March 2005, following the 11th Circuit's decision overturning the Commission's opinion in *Schering*.

The Commission has collected settlement agreements from each of these three periods of time. One set of agreements was collected for use in the preparation of the Commission's 2002 study of generic entry.[18] For this study, the FTC collected data about all ANDA filings made between 1992 and 2001, and pharmaceutical manufacturers were required to produce all patent litigation settlements that they entered into on these products during the period from January 1992 through December 2001. These agreements therefore fall in both the first and second periods of antitrust

Tables 1 and 2 provide summary information about the agreements collected for the FTC's generic drug study and in each fiscal year since passage of the MMA.[20] In Table 1, we classify agreements collected in each time period according to whether they (1) restrict entry of the generic product and include a payment from the branded manufacturer to the generic manufacturer, (2) restrict entry of the generic product and include no payment from the branded manufacturer to the generic manufacturer, or (3) include no restriction on entry of the generic product.

<insert Table 1 here>

An examination of Table 1 suggests that the terms of settlement in patent litigation in the pharmaceutical industry have changed over time. Fully one third of the agreements produced in the FTC's study of the generic drug industry involved both an agreement by the generic producer to restrict entry and the payment of compensation from the branded manufacturer to the generic firm. Furthermore, these 9 agreements were all entered into prior to late 1999, when the FTC's concerns became known publicly. In fiscal year 2004, on the other hand, there were no such agreements, although there were still settlements on terms that either included a restriction on generic entry and no compensation or involved no restriction on entry. Beginning in fiscal year 2005 – during which the FTC's *Schering* decision was overturned by the 11th Circuit – the pendulum appears to have begun to swing back the other way, as settlements that include both restrictions on entry and compensation to the generic manufacturers begin once again to appear. In fiscal year 2006, fully half of the relevant agreements disclosed to the FTC include both of these elements.

<insert Table 2 here>

[20] For more information, see "Summary of Agreements Filed in FY 2004," at http://www.ftc.gov/os/2005/01/050107med

In Table 2, we summarize information about the type of compensation that has flowed from the branded manufacturer to the generic firm in those settlement agreements that include both a restriction on entry of the generic product and a payment of compensation. As noted above, that compensation can take different forms. While paying cash alone is simplest, compensation for a delayed entry date could also potentially be included in a side deal that is not directly related to the product or issue in the underlying patent litigation. Alternatively, compensation could take the form of an agreement by the branded drug manufacturer to relinquish its right to market an authorized generic product.[21]

Table 2 strongly indicates that the form of any compensation paid to generic manufacturers in exchange for delaying the entry of their products has changed significantly over the three eras of antitrust enforcement. The early settlements that were identified in the FTC's study of generic drug entry generally included simple cash payments from the producer of the branded product to the generic firm. The only exceptions were the agreements at issue in the *Schering* case, in which the generic fi

3 Behavioral Economics and Consumer Policy

We now move from models in which firms make rational, well-considered decisions regarding litigation under uncertainty, to situations in which individuals sometimes make choices in response to viscerally tempting offers from marketers of consumer goods and services. Behavioral economics attempts to bring insights from psychology into traditional economic thinking, typically to account for limits on the rationality, will power, or self-interest of economic actors (Camerer, 2007). Behavioral economics is a very active field within economics today. It has been applied most extensively in finance, in an effort to explain stock market and other financial anomalies,[23] but behavioral economic ideas have spread to many other areas, including consumer policy.[24]

As a primary federal consumer protection agency, the FTC has followed developments in behavioral economics, and in traditional consumer and information economics more generally, because making effective consumer policy decisions requires a deep understanding of how consumers make decisions in markets and how markets respond to those decisions. Moreover, as a small agency, the FTC must decide where to allocate its resources – which consumer problems are most productively addressed by consumer policy or education, and which remedies are most effective without inhibiting other productive activities.

As part of this on-going effort, in April 2007 the FTC's Bureau of Economics sponsored a conference that brought some of the leading researchers in the behavioral economics field together with economists and others working directly on consumer policy issues in the US and in other nations. The goal of the conference was to explore the developing insights from behavioral

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economics and their potential implications for consumer policy.[25] The exchange was lively and thought provoking.

The conventional economic model views consumers as bounded by the various costs of acquiring and processing information, but it assumes that those consumers make rational decisions within those bounds. Consumers know their own preferences and have the ability to make choices in a consistent manner refl

economic model, while other situations trigger responses that are more intuitive.[27] These intuitive methods can sometimes lead consumers to make systematic errors that result in poor choices. Behavioral economists argue that understanding these behaviors is important to understanding consumer choice and, in a consumer policy setting, to designing good policy.

Under either the traditional or behavioral approach, recognition of these issues leads to an understanding that the method of presenting information, as well as the information itself, should be a focus of analysis. Marketers and educators learned long ago – and conference participants agreed – that more information is not necessarily better. A structured, simplified presentation of key information about a product may be far more useful to consumers than a comprehensive listing of many features that may be too costly to absorb and assess. Moreover, insights from the behavioral literature suggest that the framing of the information, as a positive or a negative, or as an absolute or a comparative, for instance, could affect consumer in

3.1.1 Deception Policy at the FTC

Deception policy is the more straightforward of the two, but even here the issues are not trivial. The easy cases involve false claims and fraud, which the Act clearly prohibits. The Act also prohibits deceptive claims more broadly, but this policy has evolved substantially over time. Early in the enforcement history of the Act, the agency adopted a very broad interpretation of its authority and brought enforcement actions against many claims, including, for instance, those judged to have the capacity to mislead the "ignorant, unthinking, and credulous."[30] But such a broad interpretation raised serious concerns that most marketing claims might be actionable, given the abbreviated form needed for marketing media, and this could discourage otherwise truthful claims that play an important role in informing consumers and spurring competition. Over time, the development of cases at the agency reflected these concerns, and by 1983 the Deception Policy Statement more precisely defined deception as a "… representation, omission, or practice that is likely to mislead the consumer acting reasonably in the circumstances, to the consumer's detriment."[31]

The Agency today assesses deception under this policy by considering the claims that consumers receive from an ad, judged in the context of the ad and background information. In that sense, the policy incorporates behavioral problems that consumers might have in a particular circumstance. For instance, the agency might find an ad deceptive if the ad frames the claim in a way that misleads substantial numbers of consumers on a material issue. Similarly, if copy tests show that a significant percentage of consumers misunderstand claims about particular types of risk or intertemporal issues, the agency might require more effort from the firms that are making claims on those issues to avoid the deception. These issues are judged from the perspective of targeted consumers, and, once a claim is found to be deceptive, injury to consumers is usually assumed to exist. Consumer testing, typically with controlled copy tests, is a relatively standard part of

[30] See, for instance, Aronberg v. FTC, 132 F.2d 165 (7th Cir. 1942) or Charles of the Ritz Dist. Corp. v. FTC, 143 F.2d 676 (2d. Cir. 1944).

[31] Appended to Cliffdale Associates, Inc. 103 FTC 110, 174 (1984).

assessing the claims that consumers take away from an ad when the claim is not reasonably obvious in the ad.

3.1.2 Unfairness Policy at the FTC

Unfairness policy at the FTC has also evolved substantially over time in a manner that reflects economic concerns. In its 1964 proposal to regulate cigarettes, the commission set forth criteria to judge "unfairness."[32] These included: (1) whether the practice "offends public policy" as set forth in "statutes, the common law, or otherwise"; (2) "whether it is immoral, unethical, oppressive, or unscrupulous"; or (3) "whether it causes substantial injury to consumers." In the 1970s, the agency initiated a series of rulemakings under these far-reaching criteria, culminating in a proposal to limit television advertising to children, including a possible ban of all advertising to children.[33] This agenda generated considerable hostility from business. Entire industries attempted to get exemptions from the agency's authority. More importantly, Congress became sufficiently agitated that it did not reauthorize the agency for 14years.[34]

This period of tumult led the agency to reconsider the proper focus of its unfairness authority, ultimately resulting in a move away from "public policy" as a defining criterion and towards consumer injury and consumer choice as the appropriate focus. In December 1980, a unanimous commission formally adopted the Unfairness Policy Statement declaring that injury "must be substantial; it must not be outweighed by countervailing benefits to consumers or competition that the practice produces; and it must be injury that consumers themselves could not reasonably have avoided."[35][35] The agency noted that it would only consider public policy as subsidiary

[32] "Unfair or Deceptive Advertising and Labeling of Cigarettes in Relation to the Health Hazards of Smoking," Statement of Basis and Purpose, 28 Federal Register 8355 (1964).

[33] See "FTC Staff Report on Television Advertising to Children," February 1978, and "Notice of Proposed Rulemaking on Television Advertising to Children," 43 Federal Register 17,967 (1978).

[34] For a more complete discussion of the FTC's unfairness authority, see Beales (2003).

[35] See "FTC Policy Statement on Unfairness," Appended to International Harvester Co., 104 F.T.C. 949, 1070 (1984). See 15 U.S.C. § 45(n).

interfere with public health messages.[36] But prohibiting the claims reduces a potentially large source of information on diet-health issues, and reduces firms' incentives to improve products in these dimensions.

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high in total fat and calories, which would contribute to weight gain and affiliated health problems unless the products substitute for less healthy alternatives. The evidence from the study showed no support for this deception hypothesis, adding to the evidence for a change in policy.[39]

Another area of empirical research at the Commission relates to mortgage and other credit markets. The FTC has enforcement responsibility for deception and unfairness by nonbank lenders, such as mortgage companies. In recent years, the agency has brought a number of deceptive lending cases. Those cases raised our concerns that the current federally required disclosures do not provide effective information on loan products in a timely manner.[40]

This led to several activities in 000currenDl8fte yd1005 thdevoh

that the compensation disclosure misdirected consumers' attention and led consumers to make systematic errors, including choosing loans that were more costly.[41]

More recently, we examined mortgage disclosures more broadly. This new study used in-depth interviews with three dozen recent mortgage borrowers to devise a simplified, structured disclosure of mortgage terms and compared it to current federally required disclosures. In controlled tests with over 800 participants, consumers were better able to extract key information on loan products and better able to identify lower cost loans with the redesigned form. This study provides additional evidence that the selection and format of information is an important component of consumers' ability to use disclosures.[42] Because the authors examined both simple and complex loans, and loans from prime and subprime lenders, the study is a timely piece of research with implications for the recent problems in the subprime lending market that raised issues about borrower information and about incentives along the chain from borrower to broker, to lender, to packager, and to investor.

3.3 Concluding Remarks

Behavioral economics has long argued that the framing of information can have important effects on consumer decisions. Some of our empirical research also indicates that the format and content of information can be important ingredients to consumer decision making. Whether this meld has to cwg. (portant)TJ 0.0003 Tc –0.0.02c 0.0aT imntl Td disatd disv(s ryion)65 Td reseTd [s and 725 Tx is due to behavioral considerations or to simply reducing consumers' cost of absorbing and using the information is an interesting, but unanswered question.

Behavioral economics is enriching our understanding of how consumers make decisions and could potentially alter choices about appropriate consumer policy. That stated, the field has to

correct them. And consumers themselves have incentives to learn in situations where they repeatedly make choices that are counter to their interests.[43] The challenge is to find policy approaches that facilitate that learning, and discipline the worst abuses of consumer psychological limitations, without unduly limiting consumer choice and without imposing large costs on the taxpayer, on markets, or on consumers who are not subject to the foible.

4 Conclusion

Economists at the FTC examine a wide range of competition and consumer protection issues. In this year's article we have focused on the potential effects of patent dispute settlements on entry into various pharmaceutical markets and the evolution of those patent settlements in recent years. The effects on consumers of recent settlements may not always be benign. In addition, we examined some aspects of the intersection of behavioral economics, the economics of information, and the FTC's consumer protection enforcement. The empirical evidence on the psychological aspects of human decision-making provides potentially important insights into consumer behavior at the individual level. The behavioral literature's current focus on whether and where consumer learning can overcome these behavioral problems and how these traits affect behavior in market settings will be important in judging their proper role in shaping consumer policy.

[43] See Miravete (2007), for instance, for evidence of learning from telephone contracts and Agarwal et al. (2006) on learning, and forgetting, in the credit card market.

Figures and Tables

Figure 1: Settlement When the Parties Bargain Over an Entry Date

Figure 2: Settlement When the Incumbent Can Compensate

Figure 4: Settlement with a Relatively Optimistic Generic Entrant

	FTC Generic Entry Study	FY 2004 MMA Filings	FY 2005 MMA Filings	FY 2006 MMA Filings
Restrictions on Entry and Payment of Compensation	9	0	3	14
Restrictions on Entry and No Payment of Compensation	6	5	1	6
No Restriction on Entry	9	9	7	8
Total	24	14	11	28

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