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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1 Introduction

The Federal Trade Commission's (FTC) Bureau of Economics (BE) is composed of 70 PhD-level economists, a small cadre of accountants, and 25 other staff who support the FTC's two missions of promoting competition (antitrust) and protecting consumers. The bulk of the work done by the Bureau is related directly to law enforcement activities, such as case investigation or litigation support. Other activities involve policy analysis and research related to the missions. That research buttresses our efforts in promoting competition-based policies at the state and federal levels and in fostering coordination in policy development and law enforcement around the globe.

Last year's contribution to the Antitrust and Regulatory Update program covered a wide variety of subjects but focused on economists' roles in providing empirical evidence for mergers in consumer goods and hospital industries, post-Katrina gasoline pricing, competition advocacy in pharmaceutical distribution, and our work on ID Theft issues. This year we will focus on a smaller set of topics, including a controversial aspect of pharmaceutical markets: the settlement of patent litigation and its effects on entry by generic drug firms. In addition, we will discuss our recent conference on behavioral economics and how the learning that is occurring in that field might be used to shape our consumer policies.

Before initiating that discussion, we note that economists at the FTC have been active in several areas this year, including merger review and international policy coordination and training. In the international sphere, we had one economist serve as a liaison to eastern Asian nations for six months, shuttling between Jakarta, Indonesia, and Ho Chi Minh City, Vietnam, to spread the message of competition and consumer protection to the new agencies in those areas. Several other economists participated in shorter training trips abroad and many helped with training in the U.S., when foreign colleagues made visits to better understand how we handle competition and consumer protection issues.

On the merger front, the dollar volume of general merger and acquisition (M&A) activity has once again grown to near record levels. Much of the activity during the past three years has been

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 Litigation

2.1 Introduction

The settlement of patent litigation between branded and generic drug manufacturers has emerged in recent years as an important and controversial antitrust issue. On one side, the FTC and others have argued that some firms have entered into agreements that have harmed consumer welfare by delaying the entry of generic versions of branded pharmaceuticals. The crux of the FTC's argument is that a branded drug's manufacturer and its potential generic competitors have an incentive to increase their joint profits by delaying the onset of generic competition, and they can use patent settlement agreements to implement this strategy and divide the resulting financial payoff. On the other side, pharmaceutical companies have argued that the settlements that they have reached enhance competition in a variety of ways – e.g., by resolving costly and uncertain patent litigation, and in many cases by permitting entry of a generic product before expiration of the patent or patents at issue in the litigation.

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, see also Abbott Labs., Dkt. No. C¬3945 (May 22, 2000) (consent order); Geneva Pharm., Inc., Dkt. No. C-3946 (May 22, 2000) (consent order); Hoechst Marion Roussel, Inc., Dkt. No 9293 (May 8, 2001) (consent order); and Bristol-Myers Squibb Company, Dkt. No C-4076 (April 14, 2003) (consent order).

[2] See In the Matter of Schering Plough Corporation, et al., Dkt No. 9297 (December 18, 2003) (final decision of the Commission).

[3] See In the Matter of Schering Plough Corporation, et al., Dkt No. 9297 (April 2, 2002) (Decision and Order).

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.

Patent infringement cases between branded and generic pharmaceutical manufacturers arise in a complex regulatory framework, the terms of which undoubtedly influence the nature of the settlements that the firms reach. Nevertheless, the basic economic argument for why these settlements can create antitrust concerns can be seen in a simple model, to which we now turn.

2.3 A Model of Patent Settlements

Suppose that a branded pharmaceutical company sells a product that is protected by a patent with a remaining nominal and economic life of ten years.[7] A single generic manufacturer has developed – but has not yet started to sell – a competing version of the branded product, and the incumbent branded firm has sued for infringement. If the parties litigate their case to a final conclusion, the generic firm will be able to enter with its product if the court finds either that the patent is invalid or that the entrant's product does not infringe. Reflecting the probabilistic nature of the property right that a patent grants, let us suppose that there is a 50 percent chance that the court would find the patent to be invalid or not infringed by the entrant's product.[8]

Under the assumption (for simplicity) that litigation is instantaneous, if the parties proceed to a trial, there is a 50 percent chance that the generic firm will be able to enter immediately and a 50 percent chance that it will not be able to enter for 10 years, at which time the relevant patent expires. Litigation thus offers five years of expected competition. Setting aside the effects of discounting and the growth or decline in the sales of the product, if both parties are correctly informed about the litigation odds, they should be willing to accept a settlement that allows the generic firm to begin selling its product on an entry date five years in the future, since neither would expect to do better by proceeding to court. If litigation costs are non-zero, the generic entrant would in fact be willing to accept a somewhat later entry date, and the incumbent would be willing to accept a somewhat earlier entry date, so the actual date that they reach in a

[7] While the nominal and economic life of a patent may coincide, that is not always the case. For example, new technology may displace a patented invention before the end of the patent's term.

[8] See Lemley and Shapiro (2005) for a discussion of the "probabilistic" nature of intellectual property rights. As they point out, a patent is not an iron-clad right to exclude a competitor. It is instead a right to try to exclude a competitor.

settlement would lie somewhere in an interval around the five year mark. In Figure 1 we illustrate the range of possible settlements, which is bounded by the parties' reservation entry dates.

<insert Figure 1 here>

If litigation costs are small relative to the stakes of the litigation, or if the parties have equal bargaining power in their negotiation over the surplus created by settlement, we would expect the parties to reach a settlement that would allow entry in approximately five years. Such a settlement would be consistent with the underlying merits of the litigation, and it would leave consumers roughly as well off in expectation as they would have been had the parties litigated their case to a conclusion. Such a settlement would thus satisfy Shapiro's (2003) proposed standard that a settlement of an intellectual property dispute, including a settlement for a license that permits delayed entry by a potential entrant, should satisfy a simple rule to pass antitrust muster: Expected consumer surplus must be at least as large under the settlement as under continued litigation.[9]

An examination of the parties' incentives suggests that their negotiation would be affected significantly if it were possible for the incumbent to compensate the entrant for accepting a later entry date. Suppose that the incumbent branded firm earns $10 million per month before generic entry occurs, and suppose that the incumbent and the generic entrant would each earn $3 million per month following generic entry. Then the incumbent would be willing to pay up to $7 million in order to delay generic entry by one month, and the generic entrant would accept as little as $3 million in exchange for a one month delay. This divergence between the parties' valuations of a

[9] From an economic point of view, this is a sensible standard, even if it might be difficult to implement in some circumstances. The courts, however, do not universally agree that this is the right standard. In the 11th Circuit's decision in the Schering case, the court appears to adopt the view that any patent settlement that permits entry at any time within the nominal term of the patent is acceptable. Such a standard essentially treats patents as iron-clad, both with respect to validity and infringement claims, and it could enable incumbent firms to routinely prevent competition before the end of the economic life of a patent.

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 $UB(\sigma)$ and $UG(\sigma)$ 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 σ. Both firms prefer settlements in the shaded region to σ.[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 the total profits that they could split. Consumers, of course, are made worse off relative to the litigation alternative if the parties delay generic competition beyond the date that reflects the expected outcome of the trial.

<insert Figure 2 here>

In this simple example, the standard proposed by Shapiro (2003) would disallow any settlement to the right of the curve Z in Figure 2; these agreements provide consumers with less than the five years of expected competition they would receive from litigation. As the figure is drawn, there exists a small set of settlements to the left of the curve Z that both parties would prefer to σ and that also include a payment from the incumbent to the entrant. Furthermore, these settlements leave consumers at least as well off as they would be if the parties litigated their case to a conclusion. Yet one might question whether firms would actually choose any of these settlements, at least absent effective antitrust enforcement that could reliably and verifiably determine the location of Z. Consider Figure 3, which depicts a hypothetical settlement σ^* that leaves both the parties and consumers at least as well off as they would be under the litigation

[10] The entry of a new product does not always reduce total profits. The appearance of an improved product may, for instance, cause demand to expand and total profits to increase. The entry of a generic pharmaceutical, however, is generally profit-destroying, because of the price competition that it promotes. There is a substantial economic literature on the effects of generic competition. See, e.g., Caves et al. (1991), Grabowski and Vernon (1992, 1996), Frank and Salkever (1997), Ellison et al. (1997), Wiggins and Maness (2004), and Reiffen and Ward (2005).

[11] The branded firm's profits are increasing to the southeast of $UB(\sigma)$, and the generic firm's profits are increasing to the northwest of $UG(\sigma)$.

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 court adopted a standard that would bless any settlement that included an entry date in this range, the parties would prefer to move to a settlement in the shaded region to the northeast of σ^*, and it would be reasonable to expect that they would in fact choose a settlement that permitted entry at the latest possible date: at the seven year mark in this example.

<insert Figure 3 here>

The FTC's position has been that allowing patent settlements that include both compensation from the branded drug manufacturer to the generic company and that set an entry date for the generic product would offer the parties an opportunity to trade delay for money in the manner depicted in Figure 3. If the parties could reach a settlement that approximated the expected outcome of the litigation without the payment of compensation to the generic firm, then it is plausible that the branded company must be securing a later entry date if it is willing to make a payment to the generic firm.

It is important to note that, while money is clearly the most flexible medium of exchange that the incumbent could use to compensate the generic entrant for accepting a later entry date, it is not the only possibility. Any transfer of net consideration from the branded firm to the generic firm could potentially be used to secure a later entry date for the generic firm's product. For example,

[12] The curves $U_B(\sigma*)$and $U_G(\sigma*)$ represent iso-profit curves of, respectively, the branded and generic firms that identify the sets of settlements that leave each as well off as the settlement labeled $\sigma*$.

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 products that were produced or developed by Upsher-Smith. The FTC alleged that at least a portion of this payment was, in fact, to secure the entry date that Upsher-Smith accepted. Schering, on the other hand, argued that the payment was only for the licensed products. Only one of those products – an extended-release niacin product called Niacor-SR – appeared to have any significant value. The Commission ultimately concluded that "the magnitude of the payment was not based on Schering's evaluation of the Upsher licenses."[13] Because such licenses do not always have clear market valuations, they may frequently provide a vehicle that the parties could use to transfer net consideration from the branded manufacturer to the generic entrant.

Critics of the FTC's action in *Schering* argue that parties may sometimes be unable to secure a settlement unless the incumbent is able to transfer net consideration to the entrant, or unless the parties are able to enter into a side-deal.[14] At its core, this argument rests on the existence of some factor that causes the earliest entry date that the incumbent branded firm will accept to be later than the latest entry date that the potential generic entrant will accept without some other form of compensation. For instance, the parties may disagree about the underlying merits of the case. If the entrant is relatively optimistic about its chances of prevailing at trial and expected litigation costs are sufficiently small compared to the stakes at issue in the case, there may be no range of entry dates that would be mutually acceptable to the two parties.[15]

Suppose in the previous example that the entrant believed that it had a 70 percent chance of prevailing in court, while the incumbent believed that there was only a 50 percent chance that the

[13] See In the Matter of Schering Plough Corporation, et al., Dkt No. 9297 (December 18, 2003) (final decision of the Commission), p. 79.

[14] See, e.g., Willig and Bigelow (2004).

[15] See Rubinfeld and Cooter (1989) for a discussion of how differing expectations affect the settlement of litigation.

entrant would win, and suppose that litigation is costless. Then, as illustrated in Figure 4, the entrant would only be willing to accept an entry date that is earlier than three years in the future, and the incumbent would only be willing to accept an entry date that is later than five years.[16] In this situation, the litigants will not be able to reach a settlement agreement on the basis of an entry date alone; there is no overlapping range of mutually acceptable settlements.

<insert Figure 4 here>

If the branded firm can pay the generic firm, however, the parties may be able to settle. In Figure 4, both litigants prefer settlements in the shaded region to the alternative of litigating their case to a conclusion. Maintaining the previous assumptions on the firms' profits, these settlements involve payments of at least $126 million from the branded product's producer to the generic firm. The earliest possible entry date would be 6.5 years in the future. Such an entry date would be later than either party's view of the expected entry date under the litigation alternative. Unless both parties are overly optimistic about the generic firm's chances at trial relative to the true probability that it will prevail, consumers are worse off under any of the settlements in the shaded region than they would be under litigation.[17]

Other factors could also undermine the parties' ability to reach a settlement on the basis of an entry date alone. For example, if the generic entrant had a relatively high discount rate, it would be more likely to require an earlier entry date than the branded firm would be willing to offer. Such a situation would be similar to the case of the relatively optimistic generic entrant. Willig and Bigelow (2004) argue that information asymmetries may also hinder settlement. They develop a model in which the incumbent branded firm has private information about the economic life of the patent at issue in the litigation. If the incumbent firm knows that the patent has a long economic life, it is unwilling to accept the early entry date that the uninformed generic

[16] The curves UB (lit)and UG(lit) represent iso-profit curves of, respectively, the branded and generic firms that identify the sets of settlements that each perceives as leaving it as well off as proceeding to litigation.

[17] Furthermore, given their respective beliefs about the generic firm's probability of prevailing at trial, both firms would believe that they were entering into an agreement that offered consumers less competition than they would expect to receive in litigation.

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.

2.4 Characteristics of Patent Litigation Settlements

Because patent litigation settlements between branded and generic drug manufacturers may harm third parties, i.e., consumers, there may be a role for policy that imposes some restrictions on the kinds of settlements that these firms can enter into. While the antitrust laws arguably already impose some limitations, the FTC's experience with the *Schering* case raises serious questions about whether the current legal regime can prevent settlements that harm consumers. Existing policy regarding patent settlements in the pharmaceutical industry may need to be modified in order to affect the terms on which firms settle. A comprehensive study of the effect of different legal regimes on patent litigation settlements is beyond the scope of this article. Nevertheless, it is still illuminating to examine some of the characteristics of the brand-generic patent settlement agreements that have been disclosed to the FTC in the last several years.

These settlements have arguably occurred over the course of three distinct periods of antitrust enforcement in this area. The first period, characterized by relatively weak antitrust enforcement,

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 enforcement in this area.

Since early 2004, the FTC has received copies of settlement agreements entered into by branded and generic drug manufacturers pursuant to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). This act requires that pharmaceutical companies file certain agreements with the FTC and with the Department of Justice within ten days of execution.[19] Included among these agreements are patent litigation settlements. Thus, the agreements filed under the MMA fall into both the second and third periods of antitrust enforcement in this area.

[18] See Federal Trade Commission (2002).

[19] For further information on the types of agreements that must be filed with the FTC, see "Pharmaceutical Agreement Filing Requirements," at http://www.ftc.gov/os/2004/01/040106pharmrules.pdf.

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/2005/01/050107medicareactrpt.pdf; "Summary of Agreements Filed in FY 2005," at http://www.ftc.gov/os/ 2006/04/fy2005drugsettlementsrpt.pdf; and "Summary of Agreements Filed in FY 2006," at http://www. ftc.gov/reports/mmact/MMAreport2006.pdf.

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 firms allegedly received payments in the context of side deals that involved the transfer of licenses from the generic firms to the branded firm.[22] The later settlements, on the other hand, generally included other forms of compensation, including a variety of different kinds of side deals, such as intellectual property licenses and agreements under which the generic firm received payments for co-promotion of the branded firm's product.

Taken together, Tables 1 and 2 suggest that prevailing antitrust policy does have a significant effect on the terms that pharmaceutical manufacturers reach in their patent litigation settlements.

[21] An authorized generic is sold by or licensed for sale by the manufacturer of a branded drug. It is chemically identical to the product that is sold with a brand-name, and it is sold under the branded drug's FDA-approved New Drug Application, rather than under an ANDA.

[22] One of these agreements also included a payment from the branded to the generic firm that was not tied to the side deal.

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

[23] For a recent review, see Barberis and Thaler (2003).

[24] For a recent compendium of applications in other areas, see Diamond and Vartiainen (2007)and Camerer et al. (2003). For a recent discussion of behavioral economics in the consumer policy setting, see McAuley (2006).

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 reflecting those preferences. Behavioral economics offers a number of challenges to this conventional model, by focusing on behavioral traits such as self-control problems, failure to process information objectively, and systematic misperceptions of the costs and benefits of prospective or risky choices.

The standard economic model has substantial empirical support as a basis for consumer policy in most circumstances. It has served us well in predicting problems that are likely to be self-correcting and policies that are likely to improve welfare.[26] But the behavioralists are pushing us to become more serious about understanding how consumers actually absorb information and make decisions, especially in situations where risk, complexity, or time are essential features of the decision.

Acquiring and absorbing information requires that consumers expend real money, time and effort; and making decisions requires even more of these resources. These information and decision costs are relevant to any economic assessment, whether traditional or behavioral. But behavioral economics goes farther, arguing that in some instances these costs actually lead consumers to revert to instinctive rather than rational decision processes, and this shift can lead to systematic errors. The basic idea is simple: Individuals are viewed as having two generic modes of cognitive function: roughly, intuition and reasoning. Certain types of problems or situations trigger consumers to adopt reasoning as their prime decision method, as in the standard

[25] The agenda and some of the presentations are on the agency web page at http://www.ftc.gov/be/consumerbehavior/index.shtml.

[26] See, for instance, Ippolito and Mathios (1990, 1996), Ippolito and Pappalardo (2002).

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 interpretation or decision modes, and thus might influence the appropriate policy response.[28]

FTC policy reflects some of these lessons, as does our research agenda. To see this, we begin by briefly describing the legal underpinnings of the agency's consumer protection authority before turning to a few examples of research in the area.

3.1 The Legal Milieu

Section 5 of the Federal Trade Commission Act[29] provides the agency's general consumer protection authority with the statement "… unfair or deceptive acts or practices in or affecting commerce are declared unlawful." Over time, cases and policy statements have narrowed and defined the concepts of deception and unfairness.

[27] See Kahneman (2003), based on his Nobel lecture, for a concise discussion of the psychological view of intuitive and rational decision processes.

[28] See, for instance, Kahneman and Tversky (1979) and Ho et al. (2006).

[29] 15U.S.C§25.

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).

evidence of likely consumer injury. In 1994, Congress codified the 3-part unfairness test and the limited role of public policy when it finally reauthorized the agency.

3.2 FTC Economic Research about Consumers

As can be seen from these brief descriptions, the view of appropriate consumer protection activities at the FTC has evolved to focus primarily on consumer injury in a market context. One can argue that this policy mimics a standard benefit-cost tradeoff, albeit one in which measurement of the effects is often (and appropriately) truncated. Understanding consumer behavior is an essential component of such analyses and has become an important component of our research agenda. Most often, the analysis proceeds from a traditional economic perspective, with an appreciation of consumers' costs and benefits of acquiring and processing information and the special economic characteristics of information in markets. Preserving consumer choice and firm incentives to provide information and to compete on various product dimensions are key parts of the analysis. But we also share some important characteristics with behavioral economists. Perhaps most important is our use of empirical evidence, including direct testing with consumers, to determine likely outcomes of various policy proposals. If consumers exhibit difficulty with certain types of problems, the effort focuses on better ways to present information that informs those consumer choices.

One area of FTC research reflects the debates about the most appropriate public policy towards health-related claims for food products. In the 1970s, both the FTC, the agency with primary responsibility for deceptive claims in food advertising, and the Food and Drug Administration (FDA), the agency with primary responsibility for food label claims, discouraged health claims that linked consumption of foods with consumers' health conditions – for example, claims that low saturated fat foods reduce heart disease risk. The agencies were concerned in part that such necessarily abbreviated claims would mislead consumers about diet-health issues and would

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.

As the FTC and FDA modified their policies on such claims, we were able to study changes in consumers' knowledge and food choices. Moreover, we could examine firms' development of new products and their focus on nutrition issues in marketing.[37] This work generally showed that marketing was an important source of information for consumers and a source of competitive pressure for firms. The more relaxed rules, subject to standard deception enforcement, served consumer interests.

In terms of behavioral issues, it is worth noting that many diet-disease issues involve sacrifices in taste today for health benefits far in the future. Behavioral economists hypothesize that consumers sometimes underweight these future payoffs.[38] Advertisers used a variety of approaches to make the future benefits more salient as they attempted to sell healthier choices (e.g., visual images of wanting to walk a daughter down the wedding aisle, enjoying grandchildren in retirement, etc.), potentially helping to address these issues.

In other work in the area, Bureau economists use experimental techniques to examine consumer interpretations of health claims. The most recent study in this line examined consumer perceptions of heart-health claims in print advertisements for a cooking oil that is low in saturated fat and a vegetable oil spread that contains no trans fatty acids. FDA regulations currently disallow some potentially useful heart-health claims in labeling for many such products. One deception-based motivation for that policy is that the heart-health claims might mislead consumers to believe that the products are healthy in all respects, when in fact they are

[36] For instance, one concern is that consumers might think that a product that has some healthy attributes (e.g., touting the heart benefits of a low saturated fat product) might lead consumers to believe that the product is healthy overall.

[37] See Ippolito and Mathios (1990)and (1996).

[38] See, for instance, Laibson (1997) for a discussion of the issue in financial decisions.

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 the area. We devoted resources to helping the U.S. Department of Housing and Urban Development (HUD) in its efforts to reform its regulations under the Real Estate Settlement Procedures Act, including efforts to allow packaging of mortgage services under the Act.

Another contentious issue in that overall reform effort was the requirement that mortgage brokers should disclose any compensation they received from lenders. The proposed disclosure addressed a concern that consumers might not realize that brokers were not necessarily acting solely in the consumer's interest. However, there are two offsetting concerns. First, disclosing the broker's compensation might distract consumers from focusing on the price that they would actually pay, which is the issue of ultimate concern. Second, this compensation disclosure would be required only for broker loans, the growing part of the market, but the same issues exist in bank loans. Thus, the issue is essentially a question of whether the added, asymmetric information improved or interfered with consumers' ability to make an informed decision in choosing mortgage loans. Our staff developed a simple consumer experiment to test the issue and found

[39] See Murphy et al. (2007). See also, Murphy et al. (1998).

[40] Behavioral economists might note that disclosures for such multidimensional products might be required if competition is not sufficient to induce voluntary disclosure of major product attributes. See, for instance, Gabaix and Laibson (2006) for a model in which voluntary disclosure is not forthcoming in equilibrium.

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 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 provide more evidence from market settings, to complement the experimental studies, to begin to address the questions about whether anomalies in the laboratory survive in a market context. Some firms surely have incentives to exploit consumer foibles, but other firms have incentives to

[41] Lacko and Pappalardo (2004).

[42] Lacko and Pappalardo (2007).

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

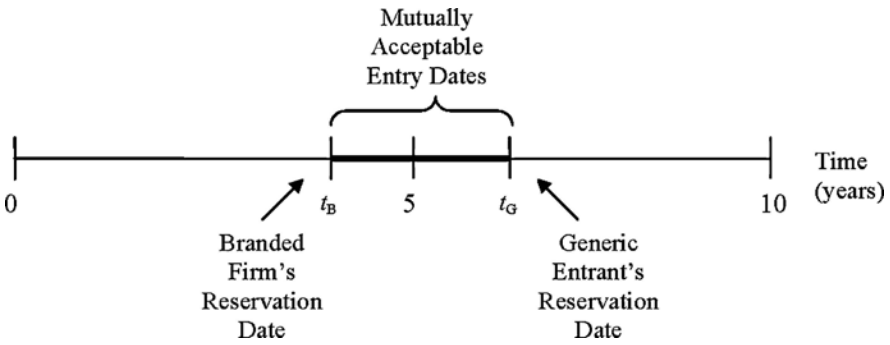

Figure 1: Settlement When the Parties Bargain Over an Entry Date

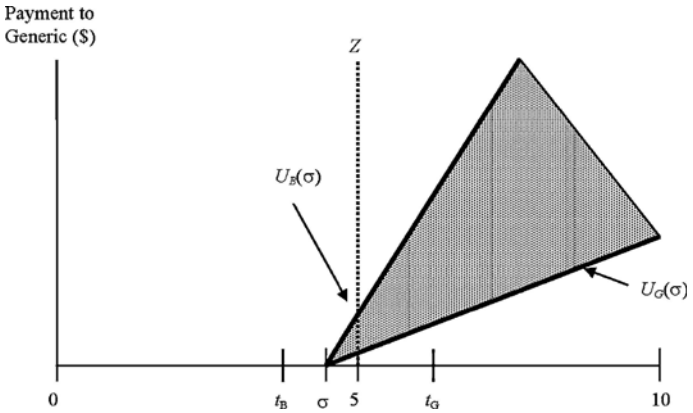

Figure 2: Settlement When the Incumbent Can Compensate the Entrant For Accepting a Later Entry Date

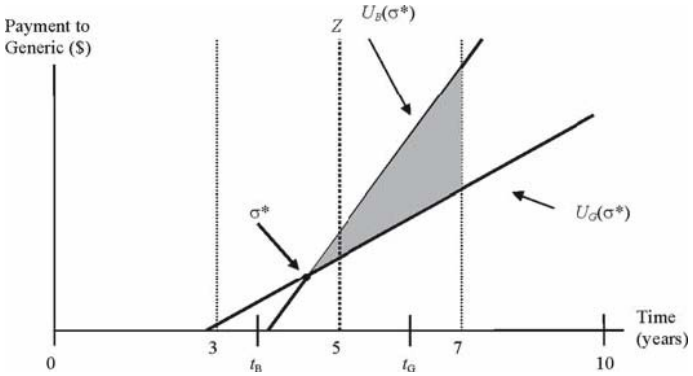

Figure 3: Settlement with Imperfect Antitrust Enforcement

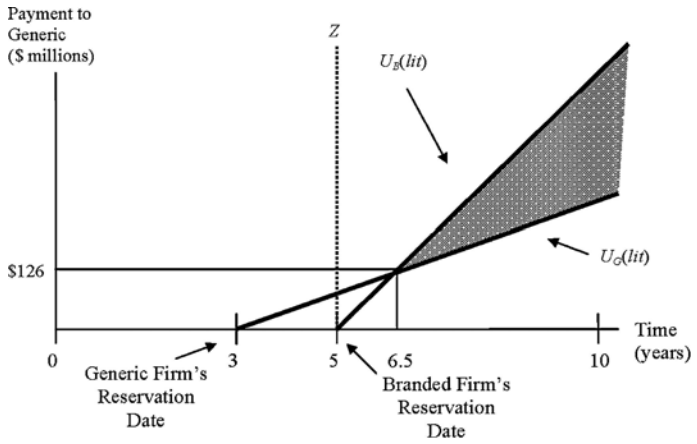

Figure 4: Settlement with a Relatively Optimistic Generic Entrant

	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

Table 1: Counts of Patent Settlement Agreements With Different Characteristics

	FTC Generic Entry Study	FY 2004 MMA Filings	FY 2005 MMA Filings	FY 2006 MMA Filings
Cash	7	0	0	1
Side Deals	2	0	2	10
No Authorized Generic	0	0	1	3
Total	9	0	3	14

Table 2: Kinds of Compensation in Patent Settlement Agreements That Restrict Entry

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