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Exclusion Payments to Settle Pharmaceutical Patent Cases: They're B-a-a-a-ck!

(The Role of the Commission, Congress, and the Courts)

I. Introduction

Let me start with the usual disclaimer that this speech does not necessarily reflect the views of the Commission or of any other individual Commissioner. Let me also start by thanking David Balto and Steve Stack for putting together this conference, inviting me to speak, and giving me the opportunity to learn a little bit more about the in-house counsel perspective.

And it is a great pleasure to be here alongside Ed Barron, who was among the first Congressional staffers to recognize the exclusionary payment problem in 1999. His leadership led to the provision in the 2003 Medicare Amendments that requires notice of pharmaceutical patent settlements to the FTC and the Department of Justice.

Some of you are not going to agree with the subject matter of my talk – that a few misguided appellate court decisions are threatening the imperfect but delicate balance of Hatch-Waxman, one that has yielded enormous benefits for consumers over the past twenty plus years. But I couldn't think of a better venue in which to test this thesis: one with smart lawyers and experts in the industry, who will challenge me if you disagree.

There are few, if any, industries that the Commission has devoted more significant resources to than the pharmaceutical industry. That makes sense. After all, health care costs are rising dramatically, and pharmaceutical spending makes up a critical component of that increase.

The Commission's successful efforts in the pharmaceutical arena – primarily over the last decade – are generally well known. They include challenging patent settlements involving collusive payments from brands to generics, prohibiting the improper listing of patents in the FDA Orange Book, insisting on divestitures in pharmaceutical acquisitions that raise competitive concerns, and issuing the oft-cited 2002 Generic Drug Study, which helped set in motion fundamental changes at the FDA and later in Congress. All of these initiatives helped protect consumers from anticompetitive harm.

We continue to focus on the pharmaceutical industry today – remaining vigilant in challenging mergers and conduct that restrict competition – whether involving brands or

generics. Last November, we sued to unwind an agreement under which Warner Chilcott paid Barr \$20 million not to enter the market with its competing generic version of the oral contraceptive Ovcon. That case is pending in federal court. And earlier this year, when Teva acquired Ivax – forming the world’s largest generic pharmaceutical company – we ordered the merged entity to sell the rights and assets to fifteen different generic products.

We also address brand-generic competition in other ways. For example, last year I urged the Commission, as did Senators Leahy and Grassley, to conduct a study of “authorized generics” – that is, generics introduced by the brand, usually at the same time the first independent generic enters the market. Since then, this practice appears to have only grown in frequency. Last month, the Commission announced that we are, in fact, going to conduct a study of authorized generics – using our 6(b) subpoena authority – to evaluate the short-term benefits of this practice against any potential long-term harm to consumers.¹

Studying authorized generics is *exactly* the kind of competition issue that the Commission was set up by Congress to evaluate when it was conceived of by President Wilson and Louis Brandeis back in 1914.² We expect to complete the study in 2007.

I also understand that some in Congress are working on proposals to address other conduct that may delay generic entry and force consumers to pay more.³ For example, the FDA uses Citizen Petitions to learn of potential problems before a product enters the market. For many years, however, there have been complaints about companies seeking to use this process to delay generic entry.

It is hard to say whether Citizen Petition abuse is a significant problem. But where the cost of filing an improper petition is trivial compared to the value of securing even a brief delay in a rival’s entry, there’s certainly an incentive to misbehave. So this is an issue that deserves consideration.⁴

¹ Press Release, Federal Trade Commission, FTC Proposes Study of Competitive Impacts of Authorized Generic Drugs (Mar. 29, 2006), <http://www.ftc.gov/opa/2006/03/authgenerics.htm>.

² President Wilson noted that the FTC was designed to be an “indispensable instrument of information and publicity, a clearing house for the facts by which both the public mind and the managers of great business undertakings should be guided . . .”. H.R. DOC. NO. 63-625, at 3 (1914).

³ One example is the recent Stabenow-Lott bill addressing Citizen Petition abuse, improper use of pediatric exclusivity, and other issues.

⁴ In 2000, the Commission provided comments to the FDA on a proposed rulemaking concerning Citizen Petitions. In those comments, we made observations concerning the potential for abusing this process, and also offered suggestions on means to minimize the potential harm from such abuse. These suggestions, if implemented by FDA or Congress, would help; but stronger provisions may be appropriate. FED. TRADE COMM’N, COMMENT OF THE STAFF OF THE BUREAU OF COMPETITION AND OF POLICY PLANNING - IN RE CITIZEN PETITIONS, FDA DOCKET NO.

II. *FTC Challenges to Pharmaceutical Patent Settlements*

Hatch-Waxman, of course, has largely been a success for consumers. To be sure, it is not invulnerable to chicanery – companies on both sides of the industry take opportunities to game the statute. For example, starting in the late 1990s, the Commission began to see pharmaceutical patent settlements in which brand firms paid generics to stay off the market. This conduct stopped, though, after we challenged several such agreements.

Having said that, recent appellate decisions that sanction this type of conduct are threatening the core of Hatch-Waxman. If the Supreme Court – or Congress – doesn't reverse this trend, the result could be a substantial increase in drug costs – and substantial harm to the consumers who pay for these drugs.

A. *The Success of Hatch-Waxman*

When Hatch-Waxman was enacted it had a few simple goals: “to make available more low cost generic drugs by establishing a generic drug approval procedure . . .”,⁵ while providing additional protections for innovator firms. The results of this law far exceeded what was envisioned back in 1984. More than twenty years after enactment, we still have a thriving pioneer drug industry – an industry that is the envy of the rest of the world, introducing new and innovative products year after year, allowing people to live longer, healthier and more productive lives. We also have a vibrant generic drug industry, one that had been virtually non-existent before Hatch-Waxman.

Let me give you a few examples of the benefits of early generic entry prior to patent expiration: generic entry on Prozac in 2001, approximately three years before the patent expired, resulted in consumer savings of about \$2.5 billion; generic entry on the heartburn drug Prilosec in 2002, more than fifteen years before the last of AstraZeneca's patents expired, saved consumers approximately \$360 million per year; and finally, generic entry on Paxil in 2003, three years before the last patent would have expired, saved consumers about \$2 billion during that period. It's clear then, that the incentives fostered by Hatch-Waxman haven't hurt industry, but have delivered substantial benefits.

B. *The Current Threat*

The unquestioned vitality of that statute, though, is being threatened by the *Schering* and *Tamoxifen* decisions. In 2003, the Commission found that Schering's payments to settle patent suits in exchange for deferred generic entry violated the FTC Act as illegal restraints of trade. We weren't the only ones to be troubled by this deal. Orrin Hatch called the Schering settlement “appalling” – on the Senate floor. On appeal, the Eleventh Circuit reversed – creating a virtual

99N-2497 (Mar. 2, 2000).

⁵ H.R. REP. NO. 98-857(I), at 14 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2647.

per se rule of legality for such payments as long as generic entry isn't delayed beyond the full patent term.⁶ We are seeking *cert*, and hope that the Supreme Court ultimately weighs in.

In *Tamoxifen*, the plaintiff alleged that Zeneca (the brand) paid Barr (the generic) \$21 million to keep its generic off the market until patent expiration. The Second Circuit, in a 2-1 decision, affirmed the district court's dismissal of the complaint. Like the Eleventh Circuit opinion in *Schering*, the majority would allow payments of any size to be made, except where the generic agrees not to market beyond the brand's patent term or where the infringement suit is a sham.⁷ The plaintiffs are seeking rehearing *en banc*, and the Commission filed an amicus brief in support.⁸

Sadly, these appellate decisions are affecting behavior in the market – we believe adversely. We are seeing far more settlements today that potentially raise competition concerns than before these decisions.

Under the 2003 Medicare Amendments, Congress required patent settlements to be filed with the FTC. Congress passed this law to “re-emphasize the Hatch-Waxman Act’s original intent of enhancing competition, not collusion, between generic and name-brand drug manufacturers”⁹ – that is, to make sure that we keep an eye on this troubling practice.

Tellingly, here's what the data for the last few years reveals from our reviews. For fiscal year 2004 – *none* of the fourteen agreements reported between brands and generics contained a payment from the brand to the generic accompanied by deferred generic entry.¹⁰ In other words, parties can – and did – settle patent litigation without money flowing to the generic.

For fiscal year 2005 – the Commission staff is releasing its report on this data today¹¹ –

⁶ *Schering-Plough Corp.*, No. 9297 2003 WL 22989651 (F.T.C. Dec. 8, 2003), *vacated*, *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005), *petition for cert filed* (Aug. 29, 2005) (No. 05-273).

⁷ *In re Tamoxifen Citrate Antitrust Litig.*, 429 F.3d 370 (2d Cir. 2005).

⁸ Brief for Federal Trade Commission as Amicus Curiae Supporting Plaintiffs-Appellants at 6-7 & n.8, *In re Tamoxifen Citrate Antitrust Litig.*, No. 03-7641 (filed Nov. 30, 2005).

⁹ Brief for Representative Harry A. Waxman as Amicus Curiae Supporting Petitioner at 10, *Fed. Trade Comm'n v. Schering-Plough Corp., et al.*, No. 05-273 (filed Sept. 30, 2005).

¹⁰ FED. TRADE COMM'N, AGREEMENTS FILED WITH THE FEDERAL TRADE COMMISSION UNDER THE MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003: SUMMARY OF AGREEMENTS FILED IN FY 2004: A REPORT BY THE BUREAU OF COMPETITION 1-2 (2005), <http://www.ftc.gov/os/2005/01/050107medicareactrpt.pdf>.

¹¹ FED. TRADE COMM'N, AGREEMENTS FILED WITH THE FEDERAL TRADE COMMISSION UNDER THE MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003:

there were sixteen settlements between brands and generics. *Three* had payments to the generic accompanied by an agreement to defer entry. This is not a surprising development – the Eleventh Circuit opinion in *Schering* came out in March 2005, midway through the fiscal year.

The most recent evidence – though not complete for fiscal year 2006 – is far more disturbing. In the six months following *Tamoxifen*,¹² more than *two-thirds* of approximately ten agreements between brands and generics included a payment from the brand and an agreement to defer generic entry. In other words, just before *Schering* and *Tamoxifen*, there were almost no payments; just after them, this appears to be the new way to do business.

Some of these settlements push the generic entry date out almost to patent expiration. A recent example reported in the press involves Plavix and Apotex.¹³ Now, most people might think these are two Roman generals but, in fact, Plavix is a widely used blood thinner with \$3.8 billion in annual U.S. sales, and Apotex is a generic drug company. One month ago, Bristol-Myers and Sanofi-Aventis (the brand manufacturers of Plavix) and Apotex settled patent litigation over this drug. The case was actually scheduled to go to trial in June, but instead they reached a compromise under which Apotex will receive monetary compensation and agree to defer entry. Apotex will enter under license from the brand firms – eight months prior to the expiration of exclusivity in November 2011.¹⁴

What was gained from this settlement? Well, for the companies it was a good deal. Their stock prices – as one might expect – rose upon its announcement. Apotex obtained a date certain to enter a huge market. Bristol-Myers and Sanofi-Aventis gained several years’ protection against potential early entry on a product that constitutes about 20 percent of Bristol-Myers’s sales.

But what was lost? Well, the potential for generic entry on Plavix before 2011, entry that estimated conservatively would have delivered hundreds of millions of dollars in annual

SUMMARY OF AGREEMENTS FILED IN FY 2005: A REPORT BY THE BUREAU OF COMPETITION (2006), <http://www.ftc.gov/os/2006/04/fy2005drugsettlementsrpt.pdf>.

¹² The *Tamoxifen* opinion issued on November 2, 2005, and the “six month” period corresponds to the first two quarters of fiscal year 2006 (*i.e.*, October 1, 2005 through March 31, 2006).

¹³ See, *e.g.*, John Carreyrou, *Bristol-Myers, Sanofi to Settle Plavix Patent Dispute with Apotex*, WALL ST. J., Mar. 22, 2006, at D5; Susan Decker, *Sanofi, Bristol Settle Apotex Lawsuit Over Plavix (Update 2)*, BLOOMBERG, Mar. 21, 2006, http://quote.bloomberg.com/apps/news?pid=10000006&sid=azIasehZ_GYI&refer=home; Peter Kang, *Bristol-Myers’ Plavix Settlement Removes Overhang*, FORBES, Mar. 22, 2006, <http://www.forbes.com/markets/2006/03/22/bristolmyers-plavix-0322markets15.html>.

¹⁴ Press release, Bristol-Myers Squibb Co., Sanofi-Aventis and Bristol-Myers Squibb Announce Agreement to Settle U.S. Plavix Litigation with Apotex Subject to Certain Conditions (Mar. 21, 2006), http://www.bms.com/news/press/data/fg_press_release_6286.html.

consumer savings. And since we are still early in 2006, assuming Apotex could have launched in the next year or so – consumers potentially lost the opportunity to benefit from these savings over several years.

Let me be clear. I have no preconceived notions about the Plavix agreement. It's just a useful example of what's at stake when generics stop fighting to enter, but instead decide to accept a truce. Curiously, and this has been noted by both the press and the parties themselves in their press release: this agreement is actually subject to "antitrust review and clearance" by the FTC under a prior consent order. And the parties acknowledged that there is "significant risk that required antitrust clearance will not be obtained."¹⁵ Our staff will take a good hard look at this – as we should – and the Commission will decide what action to take, if any.

In addition to seeing more settlements with payments today, we are also seeing another interesting trend. Brand firms are not stopping after settling with the first ANDA-filer; in some instances, they are settling with most or all subsequent filers to guarantee *no* generic entry by anyone until a date certain – one that's usually near patent expiration.

Let me give you one example. Cephalon, the brand manufacturer of Provigil, a sleep-disorder medication that garnered more than \$500 million in sales in 2005, settled pending claims with four potential generic entrants in recent months. Each of the four agreed to stay out of the market until October 2011 and will receive collective licensing payments of \$136 million. Cephalon's CEO explained the rationale: by settling with the generics, "[w]e were able to get six more years of patent protection. That's \$4 billion in sales that no one expected."¹⁶

Again, I'm offering no view on the legality of these settlements – the payments may be appropriate for the licensed IP rights. However, these settlements do deny consumers potential access to potentially major savings – here perhaps half of the \$4 billion Cephalon's CEO claims "no one" expected his company to earn. By settling with all generic applicants, a brand firm ensures that consumers never have a chance to see those savings.

To be sure, settlements are usually a good thing. From my perspective – and the perspective of many – America is too litigious a society. Too often people say, "I'll see you in court," rather than "let's work this out." And when I worked for Herb Kohl in the Senate, he had me draft his original Class Action Fairness Act, which became law in 2005. I strongly support that legislation, which was designed to reduce frivolous class action lawsuits.

But if pharmaceutical companies increasingly pay generics to stay out of the market, the goal in filing an ANDA won't be to work hard to be first to market. Instead, it will be to work hard to position yourself to be first to settle.

¹⁵ *Id.*

¹⁶ John George, *Hurdles Ahead for Cephalon*, MSNBC (Mar. 19, 2006), <http://www.msnbc.com.msn.com/id/1192057/from/RL.1/>.

We also have seen another novel strategy to bottleneck subsequent entrants. The Federal Circuit decision in *Teva v. Pfizer* held that ANDA filers who are not sued by the brand – or lack a “reasonable fear” of a lawsuit – cannot obtain a declaratory judgment about whether their product infringes or the patent is valid.¹⁷ Read in combination with *Schering* and *Tamoxifen* – and taken to its logical extent – this could mean that a brand firm, having settled with the first-filer can block *all* subsequent generic entrants simply by declining to sue. We seem to be seeing a growing trend employing this strategy¹⁸ – one that could deny consumers access to cheaper drugs until patent expiration – in other words, it’s as if Hatch-Waxman never existed in the first place.¹⁹

Why are we seeing these settlement trends? First of all, pharmaceutical firms recognize that the Commission’s view in *Schering* is under attack, and thus they believe they have less to fear from potential antitrust enforcement. If I were in-house counsel at a pharmaceutical company, that might be the way I’d view the world too.

Second, the growing use of authorized generics may diminish a generic’s incentive to fight. If a first-filer believes that the brand will sponsor an authorized generic – something that many expect today on any significant drug – the profits to be made in the 180-day exclusivity period are reduced substantially, perhaps even cut in half. So the generic firm’s calculus in the fight-versus-settle equation may now be more heavily weighted towards settling. Rather than gamble on winning in court, a generic may decide that a fixed entry date and guaranteed revenue stream is a better value than rolling the dice. Indeed, by settling under terms that include the brand’s promise not to launch an authorized generic – the generic can even assure itself of some exclusivity down the road.

By the way, such settlements may raise interesting questions regarding whether accepting delay in exchange for an assurance from the brand that the generic can enjoy its exclusivity period – without fear of competing with an authorized generic – constitutes a violation of the FTC Act.

If the *Schering* and *Tamoxifen* decisions are not reversed – that is, if branded firms are

¹⁷ *Teva Pharms USA, Inc. v. Pfizer, Inc.*, 395 F.3d 1324, 1338 (Fed. Cir. 2005), *cert. denied*, 126 S. Ct. 473 (2005).

¹⁸ Brief for Federal Trade Commission as Amicus Curiae Supporting Plaintiffs-Appellants at 6-7 n.8, *In re Tamoxifen Citrate Antitrust Litig.*, No. 03-7641 (filed Nov. 30, 2005) (hereinafter FTC Tamoxifen Amicus Brief).

¹⁹ A new forfeiture provision under the framework of Medicare Amendments – one that would trigger the first-filer’s 180-day period upon dismissal of a declaratory judgment action – would ensure that this bottleneck to generic entry does not occur. In fact, former Chairman Muris made this proposal back in 2003 when Congress was considering various 180-day triggers. Timothy J. Muris, Chairman, Fed. Trade Comm’n, Address Before the Committee on the Judiciary, United States Senate (June 17, 2003), <http://www.ftc.gov/os/2003/06/030617pharmtestimony.htm>.

empowered by the courts to pay the generic more than it would have made by competing – these rivals will have *carte blanche* to avoid competition and share resulting profits, and we will see minimal competition before patent expiration. Such results fly in the face of Congress’s efforts in 1984 to create incentives for early generic entry, and in 2003 to ensure review of these settlements that troubled them.

The practical consequences are also disturbing. Just last year, eleven generic companies were in patent litigation against brands for drugs with nearly \$25 billion in annual sales.²⁰ Early entry means billions in consumer savings; delayed entry following settlement with an exclusion payment means consumers save substantially less – and are left holding the bag.

C. *What is to be Done?*

We are optimistic that if the Supreme Court takes the *Schering* case, it will understand the implications of the Eleventh Circuit ruling – and decide in favor of the Commission, competition, and consumers. But it is not certain it will even grant *cert*. On the one hand, the Court has sought the Solicitor General’s views on this case. That’s a good sign. On the other hand, it’s not at all clear that the Solicitor General will encourage the Court to accept our petition. That’s often the death knell for *cert*.

But talk about divided government – in an unprecedented twist, should that occur, we would actually get a reply brief to our own Solicitor General. In any event, we’ll likely learn what happens in the next month or two, by the time the Supreme Court term ends.

If *cert* is rejected, the Commission will decide collectively whether (and how) to respond – we are the epitome of a consensus driven agency. However, we should think about a two-pronged approach: first, look for appropriate enforcement cases which may create a clearer split in the circuits; second, encourage Congress to act, as it has in the past.

We could bring a case in the Sixth Circuit, which has somewhat more favorable case law; in the Ninth Circuit, which is generally more receptive to antitrust claims; or perhaps in the D.C. Circuit, which has significant experience in antitrust and with enforcement agencies.²¹ As for a legislative fix, the 2003 Medicare Amendments attempted to address the competitive effects of “pacts between big pharmaceutical firms and makers of generic versions of brand name drugs[]

²⁰ FTC Tamoxifen Amicus Brief at 7-8.

²¹ My former colleague Tom Leary similarly suggested challenging patent settlements in federal district court to help foster a split in the courts. Thomas B. Leary, Antitrust Issues in the Settlement of Pharmaceutical Patent Disputes, Part III, Address Before the ABA Spring Meeting (Mar. 29, 2006), at 26, <http://www.hhlaw.com/files/News/05ac8357-7511-43c9-a927-2c7e96a0ecde/Presentation/NewsAttachment/fd869e0b-b58a-451d-ad8d-2e110dbb796b/LearyABASpringMeetingSpeech.pdf>.

that are intended to keep lower-cost drugs off the market.”²² So Congress has recognized this problem in the past; it might be willing to step in again to solve it in the future. You could write a law in a variety of ways. For example, you could ban payments above a *de minimis* amount or simply repudiate the *Schering/Tamoxifen* holdings. Determining, the best statutory approach won’t be easy, but we’ll have some time to think about this – if we have to.

III. Conclusion

Many years ago, Will Rogers said “legislation is like sausage, it comes out fine, but you don’t want to know how it’s made.” This analogy fits Hatch-Waxman – an oddity of a statute to be sure, and the only one I know that actually encourages litigation – but a law that has led to great benefits for consumers. Given those benefits, for many years it was appropriate for us to stay out of the way and let the market function – so long as the gaming was minimal and the statute remained largely in alignment. But when a law gets out of whack – as we may be seeing with the resurrection of exclusionary payments – we still have a vital role to play, whether by studying the issue or by enforcing the law.

Again, I appreciate the opportunity to share my thoughts with you. You should feel free to disagree with what I’ve said; you should feel free to do so passionately. I’m happy to hear your comments and to take questions. Thank you.

²² S. REP. NO. 107-167, at 4 (2002). Or, in the words of Representative Waxman in his recent brief supporting grant of *cert* in *Schering*, “[s]uch agreements are antithetical to the policies behind both the Hatch-Waxman Act and its 2003 amendments, which were designed to speed the introduction of generic competitors to brand-name drugs.” Waxman adds that, in enacting the 2003 Amendments, “Congress relied on the adequacy of *existing* principles of antitrust law to condemn [such] agreements. . . .” Brief for Representative Harry A. Waxman as Amicus Curiae Supporting Petitioner at 1, 13 Fed. Trade Comm’n v. Schering-Plough Corp., et al., No. 05-273 (filed Sept. 30, 2005) (citing S. REP. NO. 107-167, at 1 (2002)).